SECTION I:

OVERVIEW OF DEPARTMENTAL OPERATIONS

Overview of Departmental Operations

Our mission is to enhance the health and well-being of Americans by providing for effective health and human services and by fostering strong, sustained advances in the sciences underlying medicine, public health, and social services.

INTRODUCTION

This is the third Accountability Report for the U.S. Department of Health and Human Services (HHS), and the second as an official member of the U.S. Chief Financial Officer Council pilot program being conducted under the auspices of the Government Management Reform Act (GMRA) of 1994.

This report covers the period of October 1, 1997 through September 30, 1998 Fiscal Year (FY) 1998 and contains a high level overview of

- what we do,
- what we did with the federal funds entrusted to us, and
- how well we managed them.

It is our report to our "stockholders," the American public and as such, we are accounting for the return on the taxpayer's investment.

To substantiate what we say, the report also contains the Department's FY 1998 audited financial statements that discuss our financial condition, as well as the auditor's opinion that is an independent, objective assessment of how accurately we have represented our financial condition. Also, this comprehensive report contains many other streamlined reports required under various statutes that make us accountable for our financial, management, and program performance. This year, it also contains new information that better explains how we managed federal funds and the actual costs of our programs.

By synthesizing all of this information into this single report, we hope to provide a more complete, accurate and useful understanding of the Department. Some of our components also are issuing their own Accountability Reports; these are useful to the reader for more detailed program and finance information.

WHO WE ARE AND WHAT WE DO

The Department of Health and Human Services (HHS) is the United States government's principal agency whose mission is to enhance the health and well-being of Americans by providing for effective health and human services and by fostering strong, sustained advances in the sciences underlying medicine, public health, and social services. HHS accomplishes its mission by providing leadership in the administration of programs to improve the health and well-being of Americans and to maintain the United States as a world leader in biomedical and public health sciences.

The Department manages more than 300 programs, covering a wide spectrum of activities that impact all Americans, whether through direct services, the benefits of advances in science, or information that helps them to live better and make healthy choices. These programs include:

- Conducting and sponsoring medical and social science research,
- Preventing outbreak of infectious disease, including immunization services and eliminating environmental health hazards,
- Assuring food and drug safety,
- Providing Medicare (health insurance for elderly and disabled Americans) and Medicaid (health insurance for low-income people),
- Providing financial assistance and employment support/services for low-income families,
- Facilitating child support enforcement,
- Improving maternal and infant health,
- Head Start (pre-school education and services),
- Preventing child abuse and domestic violence,
- Substance abuse and treatment and prevention, and
- Services for older Americans, including home-delivered meals.

In addition to the services they deliver, the HHS programs provide for equitable treatment of beneficiaries nationwide, and they facilitate the collection of national health and other data for research and publication.

HHS works closely with state and local governments, private sector grantees and other partners to accomplish its programs.

- HHS is the largest grant-making agency in the federal government, providing over 56,000 grants in the amount of more than $144 billion per year (per the latest FY 1997 information).
- More than $8 out of every $10 dollars appropriated to a leading medical research organization of HHS, funds more than 50,000 investigators that are affiliated with some 2000 university, hospital and other research facilities.
- Forty-four percent of the FY1998 appropriations for American Indian and Alaska Native health services is under tribal control and significant administrative funding has also been transferred to tribal programs.
- A nationwide network of 643 community and migrant health centers, plus 144 primary care programs for the homeless and residents of public housing, serve 8.1 million Americans each year.
- Another nationwide network that includes the states and 655 Area Agencies on Aging is responsible for assessing the needs of older persons, coordinating existing resources with the more than 27,000 service providers and developing new resources to meet local priorities for services to the elderly.
- Nearly 40,000 providers of health care are certified to provide Medicare services and 22,000 employees of 66 Medicare contractors have primary responsibility for processing over 861 million Medicare claims annually.
- Some 34,000 state employees have primary responsibility for administering Medicaid.

The Department has several mechanisms in place to facilitate interdepartmental collaboration and coordination around common issues and problems among the Departments of Labor, Education, and other agencies. Some examples include:

- collaboration between HHS and Labor to implement Welfare to Work,
- co-leadership with the Environmental Protection Agency (EPA) and coordination across federal agencies including Labor and Education,
- cooperation on the Head Start program with Education, and
- coordination on the Medicare and Medicaid programs with Social Security Administration (SSA).

Children are the focus of many HHS programs.

HOW WE ARE STRUCTURED TO ACCOMPLISH OUR MISSION

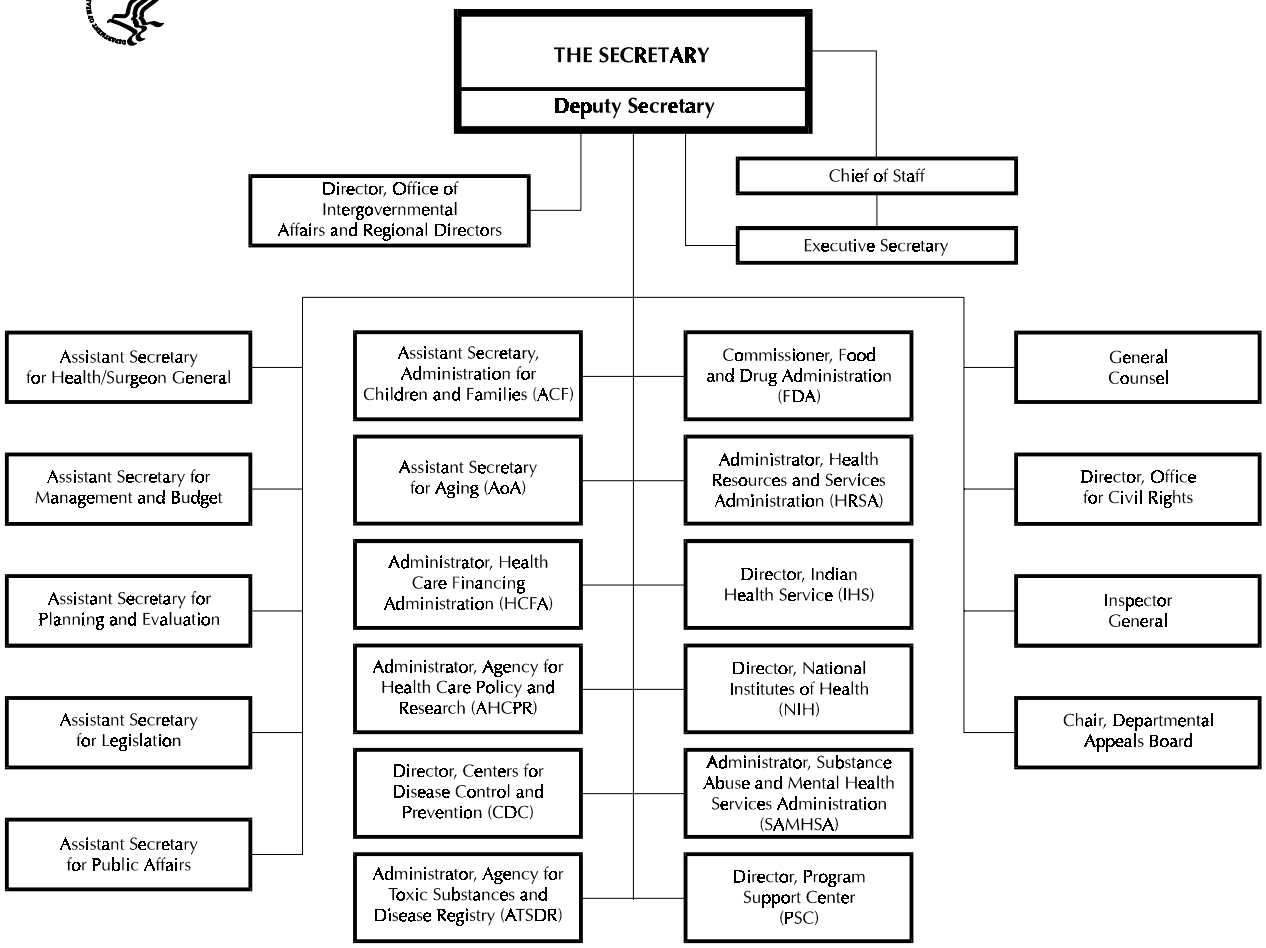
Because of the complexity and importance of the many issues involved in its mission, and consistent with the intention of congressional legislation, the Department's programs are administered by 13 HHS operating divisions. Leadership is provided by the Office of the Secretary (OS), which is also considered one of the 13 Operating Divisions (OPDIVs) and five staff divisions headed by Assistant Secretaries, including the Assistant Secretary for Management Budget (ASMB) who is responsible for this report. HHS is also active in ten regions throughout the United States, to coordinate the crosscutting and complementary efforts that are needed to accomplish our mission. This mission is also supported across the Department by offices of the Inspector General (OIG), General Counsel, Civil Rights, Departmental Appeals Board (DAB), and Intergovernmental Affairs (IGA). The FY 1998 net budget outlay for providing this leadership was $233 million.

A chart of the current organizational structure of HHS follows. There was no significant organizational change in HHS in FY 1998. HHS Headquarters is located at 200 Independence Avenue SW, Washington, D.C., 20201.

Secretary:
Donna E. Shalala

HHS FY1998 Net Budget Outlays:
$350.6 Billion

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



HHS OPERATING DIVISIONS

The HHS OPDIVs are presented in the descending order of their budget outlays for FY 1998. Budget outlays are important because they are the funds that were actually paid out for the obligations that the Federal government has incurred and are used to identify budget surpluses or deficits.

Health Care Financing Administration (HCFA)
HCFA is the largest purchaser of health care in the world. HCFA administers the Medicare and Medicaid programs, which provide health care coverage to about one in every four Americans. In FY 1998 a major new health insurance program for children was implemented cooperatively by HCFA and the states to provide health insurance, preventive health care, and other important health services to children in need.

Outlays for Medicare and Medicaid, including state funding, represent 34.2 cents of every dollar spent on health care in the United States. Medicare provides health insurance for 39.2 million elderly and disabled Americans. Medicaid, a joint federal-state program, provides health coverage for 35.4 million low-income persons, including 17.0 million children (48% of enrollees). In FY 1998 the Federal matching rates for various State and local costs averaged 56% (57% for benefits; 56% for administration). Medicaid also pays for nursing home coverage for low-income elderly, covering almost half of total national spending for nursing home care. HCFA operates from Baltimore, MD, Washington, DC, and ten regional offices. Established: 1977, incorporating the pre-existing Medicare and Medicaid programs.

ADMINISTRATOR: Nancy-Ann Min Deparle
FY 1998 NET BUDGET OUTLAY: $294 billion

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An estimated 97% of the total aged population has some type of Medicare coverage.

Administration for Children and Families (ACF)
ACF is responsible for almost 50 programs that promote the economic and social well-being of families, children, individuals, and communities. With its partners, ACF administers the new state-federal welfare reform program, Temporary Assistance to Needy Families (TANF), providing assistance to 8.9 million persons as of March, 1998. ACF administers the national child support enforcement system, collecting some $13.38 billion in 1997 in payments from non-custodial parents. It also administers the Head Start program, serving around 822,000 pre-school children.

ACF provides funds to assist low-income families in paying for child care, and supports state programs to provide for foster care and adoption assistance. It also funds programs to prevent child abuse and domestic violence. ACF is organized into 8 program offices, five staff offices that operate in Washington, DC and ten regional offices. Five regions also act as hub sites for activities that affect several regions. Established: 1991, bringing together several already-existing programs.

ASSISTANT SECRETARY FOR CHILDREN AND FAMILIES: Olivia A. Golden, Ph.D.
FY 1998 NET BUDGET OUTLAY: $31.6 billion

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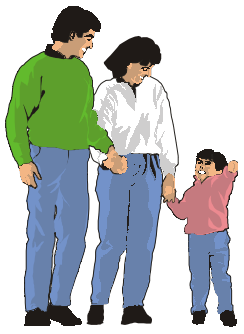


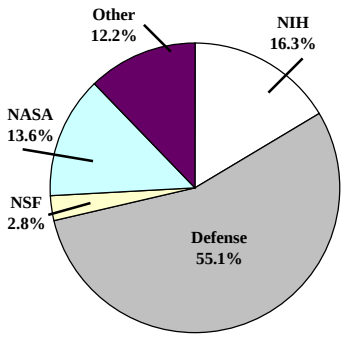
National Institutes of Health (NIH)

NIH is the world's premier medical research organization, supporting some 30,000 research projects nationwide in diseases such as cancer, Alzheimer's, diabetes, arthritis, heart ailments and AIDS. The NIH consists of 22 Institutes and Centers (ICs) that improve the health of all Americans by advancing medical knowledge and sustaining the nation's medical research capacity in disease diagnosis, treatment, and prevention. NIH's research activities extend from basic research that explores the fundamental workings of biological systems, to studies that examine disease and treatments in clinical settings, to prevention and to population-based analyses of health status and needs.

To accomplish its mission and these research activities, NIH provides scientific leadership and establishes research priorities, funds the best research in the scientific community at large, conducts leading-edge research in NIH laboratories, effectively disseminates scientific results and information, facilitates the development of health-related products, ensures a continuing supply of well-trained laboratory and clinical investigators, sustains the nation's research facilities, and collaborates with other federal agencies. NIH is located in and near Bethesda, MD. Established: 1887, as the Hygienic Laboratory, Staten Island, NY.

DIRECTOR: Harold E. Varmus, M.D.
FY 1998 NET BUDGET OUTLAY: $12.5 billion

Federal FY 1998 Research Outlays



Source: President's Budget for Fiscal Year 2000, Historical Table 9.8

NIH accounted for 16.3% of the entire Federal research budget in FY 1998.

Health Resources and Services Administration (HRSA)

HRSA is the nation's health safety net provider; HRSA improves the nation's health by assuring equitable access to comprehensive, quality health care for all. HRSA and their state, local, and other partners, work to eliminate barriers to care and eliminate health disparities for the estimated 43 million Americans who are underserved, vulnerable, and special needs populations. They also assure that quality health care professionals and services are available.

HRSA works to decrease infant mortality and improve maternal and child health. It provides services to people with AIDS through the Ryan White CARE Act programs and oversees the organ transplantation and bone marrow donor systems. HRSA also works to build the health care workforce and maintains the National Health Service Corps. HRSA uses a structure of four bureaus, a center, and special policy and support offices to accomplish its mission; its headquarters is in Rockville, Md. Established: 1982, bringing together several already-existing programs.

ADMINISTRATOR: Claude Earl Fox, M.D., M.P.H.
FY 1998 NET BUDGET OUTLAY: $3.5 billion

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Health career academic enrichment was provided for 6,800 minority and disadvantaged students. An estimated 400 students involved in minority health issue research were also supported.

Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR)

CDC is the "Nation's Prevention Agency"; it is the lead federal agency responsible for promoting health and quality of life by preventing and controlling disease, injury, and disability. CDC helps to save lives and health costs by working with partners throughout the nation and the world to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound health policies, implement prevention strategies, promote healthy behaviors, foster safe and healthy environments, and provide public health leadership and training.

CDC is well known for its response to disease outbreaks and health crises worldwide. CDC's personnel are stationed in its national headquarters in Atlanta, in 15 locations throughout the United States and territories, and in more than 20 foreign countries. CDC also provides for immunization services and for national health statistics. Established: 1946, as the Communicable Disease Center.

DIRECTOR: Jeffrey P. Koplan, M.D, M.P.H.
FY 1998 NET BUDGET OUTLAY: $2.4 billion

ATSDR helps to prevent exposure and adverse human health effects and diminished quality of life associated with exposure to hazardous substances. ATSDR is a unique component of HHS, because it is funded and therefore accountable for those funds, through the EPA Superfund account. However, ATSDR reports to the Director of CDC because of its complementary functions. Because of this, the CDC financial statements include ATSDR. ATSDR conducts public health assessments, health studies, surveillance activities, and health education training in communities around waste sites on the U.S. Environmental Protection Agency's National Priorities List. ATSDR also has developed toxicological profiles of hazardous chemicals found at these sites. ATSDR's headquarters is in Atlanta, GA. Established: 1980.

ASST. ADMINISTRATOR: Peter McCumiskey
FY 1998 NET BUDGET OUTLAY: $74 million

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Substance Abuse and Mental Health Services Administration (SAMHSA)

SAMHSA works to improve the quality and availability of substance abuse prevention, addiction treatment, and mental health services. There are approximately 44 million American adults that experience some form of mental disorder. SAMHSA provides funding through block grants to states for direct substance abuse and mental health services, including treatment for over 340,000 Americans with serious substance abuse problems. It helps improve substance abuse treatment through its Knowledge Development and Applications grant program.

SAMHSA also monitors the prevalence and incidence of substance abuse and mental illness. SAMHSA carries out its work through 3 centers and 6 offices that coordinate effort on certain special issues; its headquarters is in Rockville, Md. Established: 1992. (A predecessor agency, the Alcohol, Drug Abuse and Mental Health Administration, was established in 1974.)

ADMINISTRATOR: Nelba Chavez, Ph.D.
FY 1998 NET BUDGET OUTLAY: $2.2 billion

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Indian Health Service (IHS)

The IHS is the principal Federal health care provider and health advocate for Indian people, who experience the lowest life expectancies in the country for both men and women. In partnership with American Indians and Alaska Natives, IHS's mission is to raise their physical, mental, social, and spiritual health to the highest level. IHS and Tribes serve 1.46 million American Indians and Alaska Natives through direct delivery of local health services in 543 facilities in 35 states. There are also 34 health programs operated by urban Indian Health organizations that provide various services to American Indians and Alaska Natives living in urban areas of the country. When unavailable from IHS or the Tribes, medical services are also purchased from other providers to ensure that needed care is received.

IHS headquarters is in Rockville, MD, and its twelve area offices are further divided into service units for reservations or a population concentration. Established: 1924 (mission transferred from the Department of Interior in 1955.)

DIRECTOR: Michael H. Trujillo, M.D., M.P.H., M.S.
FY 1998 NET BUDGET OUTLAY: $2.1 billion

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Food and Drug Administration (FDA)

FDA is one of our nation's oldest consumer protection agencies. It assures the safety of foods and cosmetics, and the safety and efficacy of human and animal drugs, biological products (vaccines and blood products) and medical devices — products that represent 25 cents out of every dollar in U.S. consumer spending. To carry out this mandate, FDA monitors the manufacture, import, transport, storage, and sale of $1 trillion worth of products each year. The average cost of this effort to the taxpayer is about $3 per person. FDA's primary strategy is to ensure that safety is built into a product before a product goes on the market and that products are honestly and informatively labeled. Sound scientific analysis, regulatory standards, and communication help to ensure that industry does this; the standards are also enforced in postmarket surveillance. FDA operations are headquartered in Rockville, MD and are organized into six centers and five regions throughout the United States to accomplish its purpose. Established: 1906.

COMMISSIONER: Jane E. Henney, M.D.
FY 1998 NET BUDGET OUTLAY: $837 million

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Administration on Aging (AoA)

AoA is the federal focal point devoted exclusively to policy development, planning and service delivery to older people and their families. Through a Statewide services delivery infrastructure, AoA funds are leveraged to deliver comprehensive in-home and community services, including some 240 million meals for the elderly each year, and make legal services, counseling and ombudsmen programs available to elderly Americans. AoA accomplishes this mission in concert with its partners — the state, tribal and area agencies on aging, and the providers of services — that comprise the aging network. Established: 1965.

ASSISTANT SECRETARY FOR AGING:
Jeanette C. Takamura, Ph.D.
FY 1998 NET BUDGET OUTLAY: $828 million

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Program Support Center (PSC)
PSC is a self-supporting operating division of the Department that provides administration services for HHS and other federal agencies. The PSC is organized to provide competitive services on a service-for-fee basis, in three key areas: financial management, human resource, and administrative operations. PSC is located in Rockville, MD. Established: 1995 as a business enterprise from various administrative support units of HHS.

DIRECTOR: Lynnda M. Regan
FY 1998 NET BUDGET OUTLAY:
$247 Million – *Reimbursable.*

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Agency for Health Care Policy and Research (AHCPR)
AHCPR acts as the catalyst for improving the quality, effectiveness, accessibility and cost of health care as a result of its research and sharing of information. AHCPR conducts and supports the research needed to guide decisionmaking and improvements in both clinical care and the organization and financing of health care. AHCPR also promotes the incorporation of its and other research-based information into effective choices and treatment in health care, by developing tools for public and private decisionmakers and by broadly disseminating the results of the research. AHCPR's six centers as well as its special policy and information offices, work to achieve these results. AHCPR is located in Rockville, MD. Established: 1989.

ADMINISTRATOR: John M. Eisenberg, M.D.
FY 1998 NET BUDGET OUTLAY: $77 million

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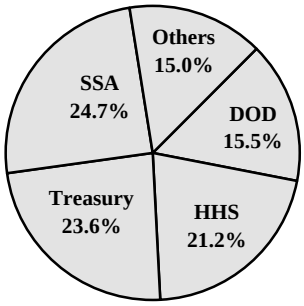
Mammograms are an important tool in detecting breast cancer.

HIGHLIGHTS OF OUR BUDGETARY OUTLAYS

In FY 1998, HHS had net outlays of $350.6 billion, representing 21.2% of all Federal net outlays. This represents an increase from $339.5 billion (21.5% of Federal net outlays) in FY 1997. Only the SSA (which became independent from HHS in 1995) and the Department of the Treasury exceeded HHS spending in FY 1998.

Federal FY 1998 Outlays by Agency

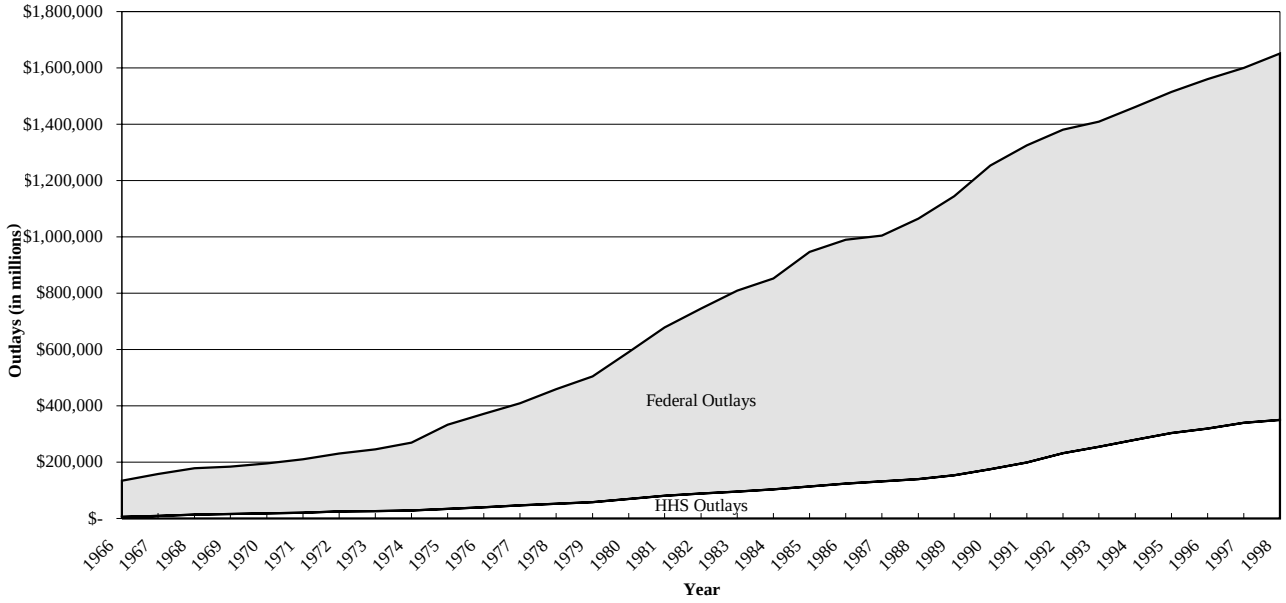


Source: Final Monthly Treasury Statement of Receipts and Outlays of the United States Government. (Treasury includes interest on Federal debt.)

The portion of the Federal budget allocated to HHS has grown significantly over the last three decades. The nature of the HHS entitlement programs is the reason for the growth in spending. We cannot limit the number of enrollees in our programs; every individual who meets the programs' criteria must be enrolled. Nine out of every ten HHS dollars are now spent on entitlements.

When the Medicare and Medicaid entitlement programs were enacted in 1966, HHS net outlays accounted for only 4% of Federal net outlays. As the ranks of the enrollees and beneficiaries of these entitlement programs has swelled along with the increasing costs of health care treatment, the impact on the Federal budget has been quite significant. *The net outlays for Medicare alone now account for 11% of the federal budget.*

Department of Health and Human Services
Outlays for the Years 1966 - 1998



Source: *Historical Tables*, Budget of the United States Government Fiscal Year 1999, Executive Office of the President

HHS FY 1998 Net Outlays by Budget Function and OPDIV
(In Thousands)

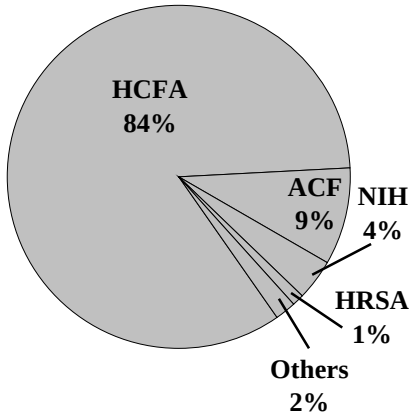
OPDIV	Education, Training, Employment, and Social Services	Health Programs	Medicare Program	Income Security	Administration of Justice	Total
HCFA	$ -	$ 101,196,791	$ 192,818,889	$ -	$ -	$ 294,015,680
ACF	12,478,753	-	-	19,065,982	39,081	31,583,816
NIH	-	12,486,139	-	-	-	12,486,139
HRSA	-	3,472,985	-	-	-	3,472,985
CDC	-	2,367,397	-	-	41,763	2,409,160
SAMHSA	-	2,235,558	-	-	-	2,235,558
IHS	-	2,144,860	-	-	-	2,144,860
FDA	-	837,010	-	-	-	837,010
AoA	827,850	-	-	-	-	827,850
AHCPR	-	76,745	-	-	-	76,745
PSC*	-	247,103	-	-	-	247,103
OS	-	232,929	-	-	-	232,929
Total	$ 13,306,603	$ 125,064,588	$ 192,818,889	$ 19,065,982	$ 80,844	$ 350,569,835

* Though PSC's services are fee-based and self-sustaining, net outlays shown include $186.2 million for Retirement Pay and Medical Benefits for Commissioned Officers with the remainder attributable to the HHS Service and Suply Fund and miscellaneoud trust funds.

HHS dollars are allocated to the OPDIVs across budget functions. The accompanying matrix chart of "HHS FY 1998 Net Outlays by Budget Function and OPDIV" details this distribution and facilitates the identification of concentrations of outlays. The largest single budget function is Medicare (which has a category all its own), with $192.8 billion in spending. The second largest functional category, at $125.3 billion, is Health where most of the funds are spent by HCFA (for Medicaid) and NIH (for research). ACF has the bulk of responsibility for budget function dollars categorized as Education, Training, Employment and Social Services, and also for Income Security through the TANF and Child Support Enforcement programs.

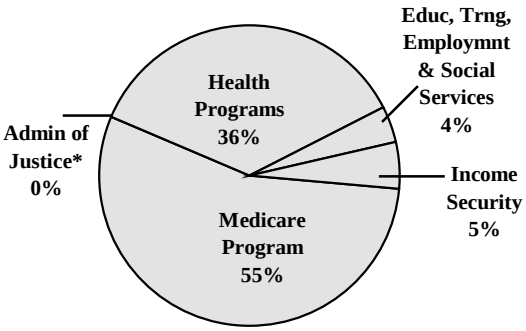
Measured by program spending, HCFA is by far the largest of the HHS OPDIVs, followed by ACF, then NIH, HRSA, CDC, SAMHSA, and other OPDIVs. Their relative portion of total HHS net outlays is illustrated in the accompanying pie chart.

HHS FY 1998 Net Outlays by OPDIV



Outlays by budget function are largely concentrated in the Medicare and Health (including Medicaid) budget functions.

HHS FY 1998 Net Outlays by Budget Function



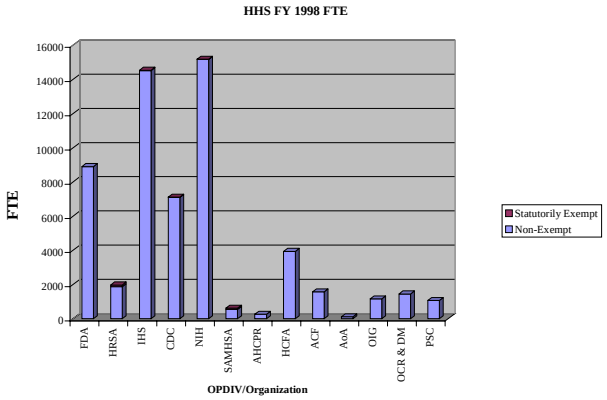
*** Less than .01%**

Readers will note that the Statement of Net Cost, a new principal financial statement for FY 1998, allocates costs by OPDIV and by budget function. Costs reported will be concentrated in a similar fashion as the budget figures for net outlays reported in this section of the Accountability Report.

Two key terms are critical to understanding of the HHS financial story. **Expenses** are one of the ingredients of the financial statements that are in Section IV. Expenses are computed using accrual accounting techniques which recognize costs when incurred and revenues when earned and include the effect of accounts receivable and accounts payable on determining annual income. **Outlays** refer to the issuance of checks, disbursements of cash, or electronic transfer of funds made to liquidate an expense regardless of the fiscal year the service was provided or the expense was incurred. Both are important in understanding the financial condition of HHS.

OUR KEY ASSET: OUR EMPLOYEES

HHS, like any organization, cannot accomplish any of its mission without its employees. They provide the necessary direct services, develop policy, coordinate with partners, award grants and contracts, and do the support functions. The following chart shows the employment level distribution within HHS. The Full Time Equivalent (FTE) measure gives a better picture of total staffing than a count of the number of people at HHS, since some work full-time and some work part-time.



The 57,898 total HHS FTE includes 227 FTE that are statutorily exempt from the FTE ceiling.

WHAT WE ARE WORKING TOWARD

To achieve improved program results and to overcome the challenges of our current, complex, and demanding environment, in FY 1997 HHS established the following strategic goals through FY 2003 and consulted on them with its partners:

HHS Strategic Goals

GOAL 1. Reduce the major threats to the health and productivity of all Americans.

GOAL 2. Improve the economic and social well-being of individuals, families, and communities in the United States.

GOAL 3. Improve access to health services and ensure the integrity of the nation's health entitlement and safety net programs.

GOAL 4. Improve the quality of health care and human services.

GOAL 5. Improve public health systems.

GOAL 6. Strengthen the nation's health sciences research enterprise and enhance its productivity.

HOW WELL WE PERFORMED

PERFORMANCE INFORMATION FOR KEY HHS PROGRAMS

In this section we discuss the performance information for key programs and initiatives of the HHS, including some program performance goals and measures for these four programs: Temporary Assistance for Needy Families (TANF), Prescription Drug and User Fee, Child Support and Enforcement (CSE), and Immunization. These goals and measures are highlighted by an 

Financial management performance information and measures are discussed in the section entitled Overview of Financial Management and other useful performance information is contained in the Reports and Other Information section of this report.

The performance information that follows is consistent with the Government Performance and Results Act of 1993 (GPRA) requirements and it supports and is aligned with the HHS strategic goals and highlighted strategic objectives. This information is also consistent with those GPRA programs discussed in the OPDIV-level financial statements, as we begin to align a program's performance with its costs. As more program performance information begins to become available with the implementation of GPRA performance reports in March, 2000, we will be able to begin to include more performance goals and measures and discuss more results of the programs.

Data on the results of our performance in various programs may be available on a limited basis and lag in time for several reasons: Data may be gathered infrequently or may not be required because of legislative intent; the reliance on third parties to provide the data; the cost of gathering the information; or nature of the data, such as research results. The availability of performance data is more fully discussed under the Challenges section of this report. Therefore some of the performance information in this FY 1998 report is for prior years because that is the most current information that is available or because that information became known during FY 1998. Trends of our performance can eventually be determined by a comparison of annual trends in Accountability Reports from year to year.

A key purpose of GPRA is to improve the confidence of the American people in the capability of the federal government by systematically holding federal agencies accountable for achieving program results.

GOAL 1: REDUCE THE MAJOR THREATS TO THE HEALTH AND PRODUCTIVITY OF ALL AMERICANS.

Good health lies at the heart of the nation's well being. A healthy work force is more productive; a healthy student body is ready to learn; and healthy people are able to build a better society. HHS investments in reducing or eliminating behavioral threats to life and good health can pay off heavily in improved health and productivity of the American people.

❖ We took steps to reduce tobacco use, especially among youth.

Every day, 3000 teenagers start smoking, and 1 out of 3 will die of smoking-related diseases.

To address this problem CDC supported 32 states and the District of Columbia in tobacco control programs. More than 200,000 retail establishments have been inspected since 1996, under a tobacco control final regulation that requires states to monitor retailers to ensure that they prohibit retailers from selling tobacco products to children, according to SAMHSA. SAMHSA's state data show that the likelihood of retailers' selling tobacco to minors has decreased from approximately 41% in 1996 to 26% in 1997.

FDA contributed to this coordinated effort by awarding contracts to some states to assist them in complying with survey requirements without placing an added burden on them. In FY 1998, ten states in all ten regions of the United States were in the initial contract stages of pilot testing the new FDA rule requiring states to conduct unannounced visits to retailers to ensure that they comply with bans on purchase of cigarettes and smokeless tobacco by adolescents under 18 years old. As a result of the effort of these and some additional states, there were 39,439 attempted and completed compliance checks during FY 1998, including reinspection of retailers found to have violated the rule.

By the close of FY 1998, FDA had signed contracts with 43 states and territories to expand the enforcement of compliance checks. All of the original ten states are continuing to participate, and in at least two states, the program was so successful that they expanded the areas of the states included in the investigations.

In February 1998, the Secretary and the Vice President launched FDA's new national education campaign that uses creative point-of-sale, radio, print, and billboard advertisements to make clear to consumers and retailers that tobacco sales to minors are against the law.

In addition, CDC collaborated with a university to evaluate ***educational intervention*** of reducing exposure of infants to environmental tobacco smoke in an ethnically diverse sample of families and found that urinary testing is necessary to determine accurate levels of exposure and effectiveness of educational efforts.

There are an estimated 3 million underaged smokers in the United States. (Dramatization)

❖ **We helped to improve the diet and the level of physical activity of Americans.**

Diet or ***Nutrition***, along with physical activity, contributes to at least four of the ten leading causes of death and disability. The costs associated with diet-and activity-related health conditions, including direct health care and lost productivity, are estimated at $56.3 billion a year. The elderly are particularly vulnerable to poor nutrition. To combat this problem in FY 1998, $486.4 million was provided to the states through the Aging Network to help serve 118.6 million ***Congregate (group or community) and*** 119.1 million ***Home-delivered meals***. These meals provided 40 to 50% of their daily intake from one meal per day, according to the 1996 program evaluation, the last year that we actually have data.

❖ **We actively promoted the reduction of unsafe sexual behaviors.**

Unsafe sexual behavior can result in ***sexually transmitted diseases*** and contributes to some of the most rapidly spreading diseases in the country. The U. S. leads industrialized countries in rates of sexually transmitted diseases (STD). Effective STD prevention has been demonstrated to reduce HIV transmission by more than 40%. In addition, unsafe sexual behavior among teens can result in unintended pregnancies and a potentially life-damaging consequence of adolescent sexual experimentation. HHS has addressed the spread of these diseases by prevention activities, surveillance, and research.

During FY 1998, the 1991-97 Youth Risk Behavior Survey was analyzed to determine sexual risk behaviors among high school students. For the first time in two decades, the rate of unsafe sexual behaviors declined and the proportion of high school students that received HIV education in school increased from 83% to 92%. These results reflect national, state, and local effort to reduce unsafe sexual behaviors.

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In 1997 11,500 ***AIDS*** cases were diagnosed. To help prevent and control the spread of the deadly virus in FY 1998, CDC funded local prevention activities, helped HIV prevention programs to improve their services by applying effective behavioral interventions, and supported researchers to help identify successful approaches that community HIV programs can use. HIV surveillance guidelines were also developed in FY 1998. There were also collaborative international efforts for surveillance with the Joint United Nations Program on HIV/AIDS.

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Also, in April, 1998, HHS announced that the ***teen birth rate*** fell an estimated 3% in 1997, continuing a six-year downward trend. This means that the teen birth rate substantially declined for virtually every ethnic group of women aged 15-19. In particular, the rate for African-American teens, until recently the highest, experienced the largest decline, down 23% from 1991 to 1997.

In addition to the prevention efforts of CDC, grants such as the Maternal and Child Health Block Grant, plus the Abstinence Education program and the Adolescent Family Life demonstration activities in FY 1998, promoted and tested promising interventions to reduce teenage pregnancies.

❖ **We worked to curb alcohol use and reduce the use of illicit drugs.**

Preliminary data indicates that the rate of drug-related deaths for the total population increased from the 1987 baseline of 3.8 per 100,000 to 4.7 in 1996. Since 1990, the drug-related death rate has increased 21% for African-Americans and 40% for Hispanics. However, according to three out of four recent government surveys, in the past two years, drug use - including marijuana use - has declined or at least leveled off.

In FY 1998, we awarded $262 million in formula block grant funds to states targeted for substance abuse prevention services. In addition, the five states that won competitive grants from SAMHSA in FY 1997 worked in FY 1998 to reverse substance abuse trends among youth aged 12-17 by developing statewide substance abuse prevention plans and implementing science-based prevention approaches and programs in communities. Each state reexamined their current programs and developed strategies to combine and leverage resources throughout the state. The five states developed common instrumentation to compare and analyze aggregated and individual state data. Fourteen additional states received grants in FY 1998 ($42 million) to begin these efforts.

Long-Term Trends, 1975-1998 – Monitoring the Future has surveyed 12th graders continuously since 1975, and notes some long-term trends for this group only.

From a peak in drug use that occurred in 1979, use of marijuana by 12th graders declined from 1980 to 1992, rose between 1993 and 1995, stabilized for a year, increased between 1996 and 1997, and remained unchanged in 1998. In 1979, past year marijuana use for 12th graders peaked at 50.8 percent; in 1998, 37.5 percent of 12th graders have used marijuana at least once in the past year.

Highlights from the 1998 Monitoring the Future Survey

This annual survey tracks 8th, 10th and 12th graders illicit drug use and also attitudes. Unless otherwise noted, all changes are statistically significant.

Any Illicit Drug Use – Past year use among 10th graders decreased from 38.5 percent in 1997 to 35.0 percent in 1998. Past year use among 8th graders decreased from 23.6 percent in 1996 to 21.0 percent in 1998.

Marijuana – Lifetime, past year, and past month use dropped among 10th graders: from 42.3 percent in 1997 to 39.6 percent in 1998 for lifetime use; from 34.8 percent in 1997 to 31.1 percent in 1998 for past year use; and from 20.5 percent in 1997 to 18.7 percent in 1998 for past month use. Rates of marijuana use among 8th and 12th graders remained stable.

Crack/Cocaine – Crack and cocaine use remained stable across the board for 10th and 12th graders. Among 8th graders, however, increases were noted in lifetime use of crack (from 2.7 percent in 1997 to 3.2 percent in 1998) and in past year use (from 1.7 percent to 2.1 percent of 8th graders).

Heroin – Heroin use remained stable across the board for each grade.

Inhalants – Past month inhalant use decreased among 8th graders, from 5.6 percent in 1997 to 1.1 percent in 1998. While inhalant use among 8th graders remains generally higher than for the other grades, use has been declining gradually in all three grades since 1995.

LSD – Past month use of LSD decreased among 8th graders, from 1.5 percent in 1997 to 1.1 percent in 1998.

Alcohol – For a few years, alcohol use has remained stable among 8th and 10th graders. Alcohol use among 12th graders had increased between 1996 and 1997, but remained stable from 1997 to 1998. In addition, some decreases were seen among 10th graders: lifetime use decreased from 72.0 percent in 1997 to 69.8 percent in 1998; past year use decreased from 65.2 percent in 1997 to 62.7 percent in 1998.

GOAL 2: IMPROVE THE ECONOMIC AND SOCIAL WELL-BEING OF INDIVIDUALS, FAMILIES, AND COMMUNITIES IN THE UNITED STATES.

Each person, regardless of age, sex, physical ability, or racial/ethnic background, should have the opportunity to lead an economically and socially productive life. With its partners, HHS supports strategies that create opportunities for individuals, families, and communities to be economically and socially productive.

❖ We worked to increase the economic independence of families on welfare.

Under the ***TANF*** program, states have extensive flexibility in designing programs that promote work, responsibility, and self-sufficiency. Almost every state requires personal responsibility contracts, with 32 states expecting clients to work within six months. In FY 1998, the federal government provided funding to the states to operate these programs. Also, we have continued to work extensively with states to promote the work objectives of the new law and improve program accountability. TANF final rules on the work participation standards, data collection, and other accountability measures are scheduled for publication this spring. A final rule on the High Performance bonus incentives is scheduled for publication in the fall of 1999.

The FY 1998 high impact target established with the National Partnership for Reinventing Government was to move 600,000 welfare recipients of the estimated 8.9 million recipients (as of March 1998) into new employment. Preliminary data for FY 1998 has been received and is being analyzed.

Welfare caseloads continued to decline in 1998. By September 1998, the caseload had dropped to approximately 8 million recipients and slightly less than 3 million families. Since January 1993, the number of recipients on welfare has dropped more than 43% (by 6.1 million), including a decline of more than 35% (4.2 million) since the enactment of the welfare reform law in August 1996.

States have not cut benefit levels in a "race to the bottom" though, as was feared.

The federal government is also helping the states and recipients by hiring new workers from the welfare rolls. HHS has hired 282 new workers from the welfare rolls and is well ahead of reaching its goal of 300 new welfare hires by 2000.

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One of the challenges to economic independence and a significant concern of working families, is adequate ***Child Care***. A total of $3.073 billion was awarded in FY 1998 to States under two ACF programs; the Child Care Development Block Grant and the Child Care Entitlement to states. In January 1998, the President announced a $21.7 billion initiative to increase subsidies and tax credits for low to middle income families, provide new resources to states to improve the quality of child care and choices for parents, and expand after school programs. The President secured a down-payment on the proposal with $200 million for the 21st Century Learning Program and $180 million for states to improve child care quality for FY 1999.

The performance goals and performance outcome, output, and process measures for affordable, quality, and available child care are being developed. The Federal Child Care Information System will electronically collect all data required to assess the success of the program.

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❖ **We helped to increase the financial and emotional resources available to children from their noncustodial parents.**

The ***Child Support Enforcement Program*** (CSE) obtains support for children by locating parents, establishing paternity, and establishing and enforcing support orders. The national employment database, known as the National Directory of New Hires, showed early success by matching selected state cases and found over 1.2 million delinquent parents. In FY 1998, HHS also worked on the Federal Case Registry, which will contain records of all parents who owe child support; it became operational on October 1.

The actual amount of child support collected in FY 1997 was $13.38 billion. This is more than an 11% improvement above the 1996 level of $12 billion. Actual FY 1998 data should be available in the spring of 1999; preliminary data for FY 1998 as of December 30, 1998, indicates the amount of collections at $14.4 billion. The FY 1998 National Partnership for Reinventing Government High Impact goal for collections is $14.7 billion.

HHS promoted state innovation in CSE with $1 million in grants to support research and demonstration projects. HHS drafted and supported through enactment, new legislation to reward states on their performance. The Child Support Performance and Incentives Act, signed into law on July 16, 1998, not only imposes tough new penalties on states for not meeting statutory deadlines for establishing automated data processing systems, but also rewards states for their performance on a wide range of child support activities. In response to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, state and federal partners collaborated to make recommendations to the Secretary on a performance-based incentive system to reward state results. These recommendations, which the Secretary forwarded to Congress, were largely enacted into law.

Children Under Age 18 as a Percent of Total Population

		Projected		
	1997	2000	2010	2020
Age group				
Under age 18	26	26	24	24
Ages 18-64	61	62	62	59
Ages 65+	13	13	13	16

Source: U.S. Bureau of the Census, 1990 Census

❖ **We supported the improvement of the healthy development and learning readiness of preschool children.**

Head Start program's performance resulted in the October, 1998 bipartisan reauthorization, strengthening and expanding of Head Start for four more years. Around 822,000 children were enrolled this past year in programs to enhance children's growth and development; strengthen families, and provide children's educational services. Funding for Head Start has increased under the current Administration and enrollment has increased by over 100,000.

Healthy Start was launched in 1991 to reduce infant mortality in areas with extremely high infant mortality and low birth weight babies. In FY 1998, $93.9 million was awarded to 20 mentoring projects, 55 phase II projects, and one national resource center. Also in FY 1998, Healthy Start funds supported 3 infant mortality/morbidity review grants.

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The Healthy Start Program focuses on the health of infants at risk.

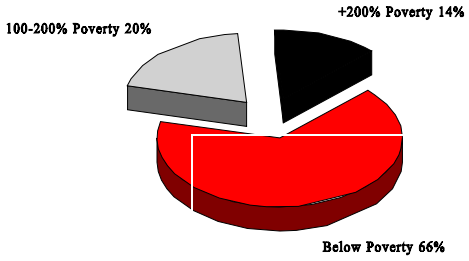
GOAL 3: IMPROVE ACCESS TO HEALTH SERVICES AND ENSURE THE INTEGRITY OF THE NATION'S HEALTH ENTITLEMENT AND SAFETY NET PROGRAMS.

Without insurance, access to health services is severely compromised. With its partners, HHS broadens access to services and maximizes the number of low-income or special–needs populations served. HHS also prevents waste, fraud, and abuse of its entitlement and safety net programs, particularly Medicare and Medicaid, because of their size and their impact on the total health care system.

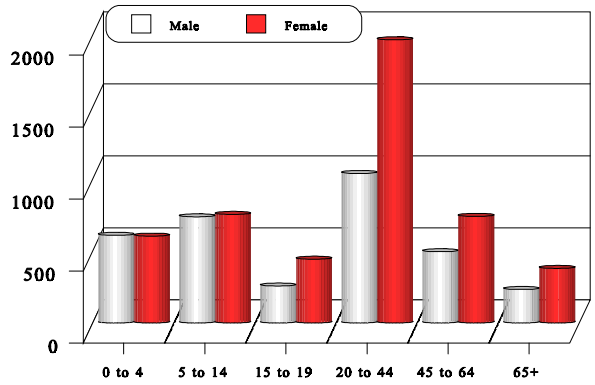
❖ **We are helping to bring about an increase in the percentage of the Nation's children who have health insurance coverage.**

Health Center Patients:

By Economic Status - 1997



By Age, Gender - 1997



In 1998, HHS worked diligently with its partners to develop and implement plans to extend health care coverage to millions of uninsured children. The ***State Children's Health Insurance Program (CHIP)***, which was passed in the Balanced Budget Act of 1997 and amendments, provides for nearly $40 billion in set-aside funds over the next ten years for health insurance for prevention and treatment care for uninsured, low-income children. Community Health Centers are responding aggressively to the opportunities offered through CHIP. HRSA and its Health Center grantees recognize that ongoing and intensified outreach and educational efforts will be necessary to assure that all the children who are eligible under CHIP are enrolled.

To be eligible for these funds, states and territories must obtain approval from the federal government for a state child health plan. In FY 1998, HCFA provided states with a procedure for plan submittal, financial reporting forms and claims procedures, coordination with Medicaid expansions for children's health, and procedures for annual reports, evaluations, and studies.

To date 48 states and territorial plans have been approved under CHIP. These CHIP plans expect to cover an estimated 2.5 million children within the next three years.

During FY 1998, the Office for Civil Rights worked with HCFA and HRSA staff in reviewing initial state CHIP plan proposals, noting problems with regard to enrollment, outreach, provision of services, availability of materials, and site accessibility for persons with visual and hearing disabilities and persons with limited English proficiency.

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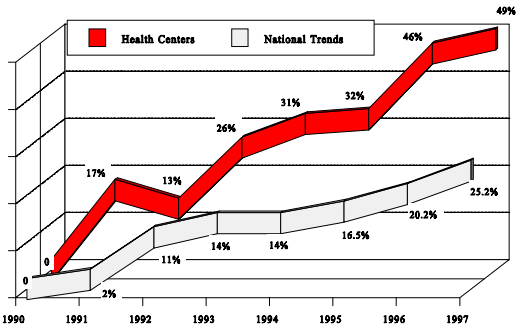
❖ **We increased the availability of primary health care services.**



Health Center Uninsured Patients Have Increased at Twice the National Rate Since 1990.

Community Health Centers and the National Health Service Corps delivered primary health care services to 10.3 million patients in FY 1998; this represents approximately one-fourth of the 43 million persons across the nation who lack access to a primary care provider. In addition, in FY 1998 efforts expanded to fund 9 new starts and 7 expansions that will serve an additional 100,000 underserved people. To accomplish this, HRSA placed 2,298 physicians, nurses, dentists, and other primary care providers in underserved communities through the National Health Service Corps.

To assure a health professions workforce that meets the health care needs of the American people, HRSA's ***Health Professions Programs*** operate more than 40 grant and student assistance activities focused on improving the diversity and distribution of the nation's health care practitioners. In 1998 this investment resulted in new graduates providing cost-saving primary care services to vulnerable populations; a more culturally competent and diverse health care workforce; and effective collaboration with academic institutions, state, and local governments, foundations, the health care industry and communities to meet pressing health care needs.

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As part of the Department's initiatives to improve access to health care, The Office for Civil Rights ensured ***nondiscriminatory access*** to health care services the quality of services by closing/resolving 1,644 discrimination complaints in FY 1998, leaving 503 of the total workload of 2,147 to be resolved.

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In response to the severe and ongoing crisis regarding HIV/AIDS, ***Emergency relief for areas dealing with the HIV/AIDS epidemic and HIV/AIDS Care formula grants*** to states and territories were funded for organizing and delivering health services, including home and community-based care, insurance coverage, and drug treatments. HHS increased by 70% the funds earmarked for the ***AIDS Drug Assistance Programs,*** (ADAP), ensuring that more than 100,000 low-income individuals living with HIV/AIDS receive life-saving and -sustaining drug therapies.

Early Intervention Services were funded at 174 programs to provide counseling and testing to over 300,000 people; outreach services to more than 700,000 Americans; and case management and eligibility assistance to nearly 80,000 citizens. The ***Pediatric HIV/AIDS*** program is effective in organizing and improving patient access to comprehensive health and social services; identifying HIV-positive pregnant women for therapies to prevent the transmission of HIV to newborns; and enrolling HIV-positive adolescents in both care and research programs.

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In 1998, an estimated 55% of the population of persons with AIDS was covered by Medicaid. Medicaid spending on AIDS in FY 1998 was $1.9 billion (federal) and $1.6 billion (state). Medicare AIDS spending in FY 1998 is estimated at $1.4 billion.

HRSA provides better health to rural America by working with federal, state and local governments and with private-sector associations, foundations, providers and community leaders to seek solutions to ***Rural Health Care*** problems. In 1998, 97 projects bringing care to at least 2 million rural citizens were supported through Rural Health Outreach grants. Forty-two Network Development grants helped community-based consortia to improve patient care, cut operating costs, capitalize on shared information and management systems, and help members survive market-driven changes. Forty-one ***Telehealth*** projects were awarded to promote the effective use of telehealth technologies to improve distance education and clinical consultation for rural and underserved communities.

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Of special concern also are health care services for mothers and children of low-income or isolated populations, who otherwise would have limited access to care. ***The Maternal and Child Health Services Block Grant*** program provided funds ($681 million was spent in FY 1998) to 59 States and jurisdictions under a matching formula that takes into consideration the percent of the nation's low-income children residing in each. Since it is a block grant, the states have discretion in how they spend the funds to meet the goals of the program, which include reducing infant mortality; increasing the number of children immunized; increase the number of low-income children receiving health assessments; comprehensive perinatal care for women; and preventive and primary child care services.

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The ***National Immunization Program*** focuses on several major programmatic areas to achieve its goals, including childhood immunization, adult immunization, and global polio eradication. State and local health agencies play a primary role by using federal grant funds for a wide variety of immunization activities, including surveillance. As a result, information that shows that immunization coverage levels for adults in the United States have increased for influenza and pneumococcal disease; and the preschool-aged vaccination rate has exceeded prior national objectives.

The 1997 Behavioral Risk Factor Surveillance System documented a 66% ***influenza*** vaccination coverage level, and a ***pneumococcal*** vaccination coverage of 45% for adults $\geq$ 65. The national health objective as outlined in Healthy People 2000 was exceeded by 45 states.

All of the national 1996 immunization coverage goals from Healthy People 2000 for ***vaccination of preschool-aged children*** have continued to be exceeded. For the annual period ending June, 1998, national immunization coverage for the most critical doses of the vaccines routinely recommended for children 19-35 months of age exceeded 90%. Most of the coverage goals for children in each of the five racial/ethnic groups were met; those not met were within one to three percentage points below the goal. In the coming years, we will be devoting increased attention to vaccination of minority children.

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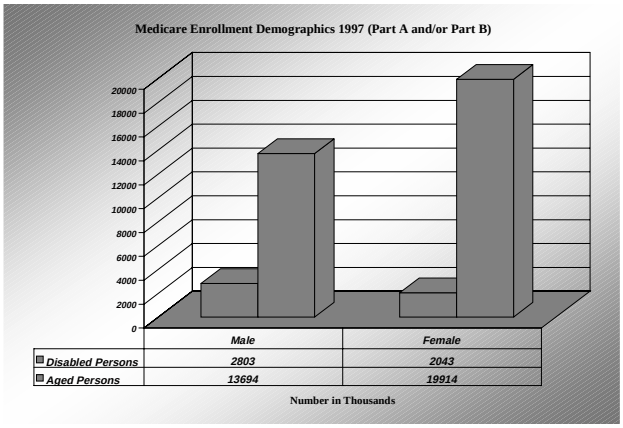
❖ **We protected and improved beneficiary health and satisfaction with Medicare and Medicaid.**

Medicare and Medicaid provide health insurance coverage for approximately 70 million elderly, disabled, and economically disadvantaged Americans.

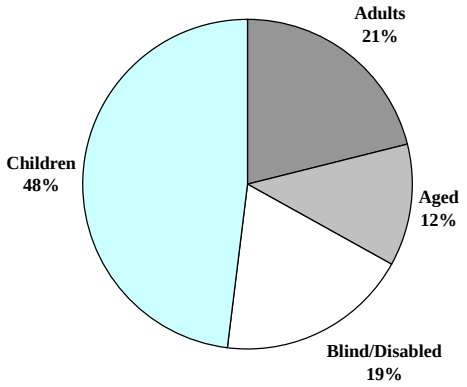
Medicare covers both hospital insurance and insurance for physician and outpatient care, laboratory tests, home health care, durable medical equipment, designated therapy services, and other services not covered by hospital insurance. A new, third program under Medicare, Medicare+Choice, was created in 1997 and restructured Medicare to increase health care options for beneficiaries

through a greater variety of managed care and fee-for-service plans. Over the last thirty years, Medicare has significantly contributed to life expectancy, to the quality of life, and to protection from poverty for the aged and disabled. In FY 98, Medicare costs were $279 billion.



Medicaid is the primary source of health care for medically vulnerable Americans, including poor families, the disabled, and persons with developmental disabilities requiring long term care. Medicaid is administered in partnership with the States; HCFA issues the matching payment grants to states and territories for medical assistance and administrative costs. Medicaid enrollees are now 12% of the population. Medicaid has improved birth outcomes, childhood immunization rates, and access to preventive services, resulting in overall improvements in the health of America's children. Medicaid also pays more than 47.6% of nursing home costs. Medicaid costs in FY 1998 were $97.97 billion.

Medicaid Recipients



In 1998, a specially developed version of the Consumer Assessment of Health Plans Survey, to ***survey Medicare enrollees in managed care plans*** to assess their experiences. The survey results will provide extensive information about currently available Medicare managed care plans. The results will be sent to every Medicare beneficiary in early 1999, helping them to make better-informed choices about their health plan options.

In September, 1998 HHS took action to ensure that ***Medicare beneficiaries with acute mental illness*** get quality treatment in community mental health centers and that Medicare pays appropriately for those services. The federal government now has the authority to begin termination actions against centers that appear unable to provide Medicare's legally required core services, and will require others to come quickly into compliance. We can demand repayment of money paid inappropriately for non-covered services or ineligible beneficiaries.

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❖ **We enhanced the fiscal integrity of HCFA programs and ensured the best value health care for beneficiaries.**

HCFA made great strides in 1998 to further define its overall ***strategy for fighting fraud and abuse in the Medicare and Medicaid programs.*** HCFA developed a comprehensive program integrity plan for use during the next 6 to18 months, based on the key payment safeguard principles for: fraud prevention, detection, enforcement, and coordination.

In 1998 HCFA also required more than 250 Medicare managed care risk-based plan (paid on a per-capita rate computed by actuaries) and cost-based plan (paid based on a cost report and audit) ***contractors to report on measures of performance*** on managed care programs. These measures included effectiveness of care, use of services, access to care, and other relevant areas that will provide a better understanding of the performance of the Medicare managed care plans.

Under the ***Health Care Fraud and Abuse Control Program***, HCFA, the HHS Inspector General, FBI, and the Department of Justice, as well as other agencies, including the Administration on Aging, are working together to detect and prevent fraud and abuse.

HHS and the Department of Justice have reported more than $1.2 billion in fines and restitution returned to the Medicare Trust Fund during fiscal years 1997 and 1998. During these years, HHS also excluded more than 5,700 individuals and entities from doing business with Medicare, Medicaid, and other Federal and State health care programs for engaging in fraud or other professional misconduct—up from 2,846 in the previous two years. In addition, HHS increased convictions in health care cases in which HHS/Office of the Inspector General participated increased by nearly 20% in 1997 and another 16% in 1998.

HHS/OIG works with HCFA to develop and implement recommendations to correct systemic vulnerabilities detected during evaluations and audits. These corrective actions often result in health care "funds not expended" (that is, funds put to better use as a result of implemented recommendations for program improvement). During FY 1998, such funds not expended on improper or unnecessary care amounted to approximately $10.8 billion. Much of this amount reflects savings achieved as a result of legislative amendments brought about by the Balanced Budget Act of 1996 and the Omnibus Budget Reconciliation Act of 1993.

On September 15, 1998, HHS announced that for the first time, Medicare will hire special outside contractors, to carry out audits, conduct medical reviews, and conduct programs that will expand the Administration's fight against waste, fraud and abuse. These contractors will work with the ***Medicare Integrity Program*** to end criminal activities by fraudulent health care providers, ensure that Medicare pays only for medically necessary services, and identify honest errors that lead to improper payments.

Fraud Hot Line
Toll Free (800) 447-8477

While we have long known there are billing abuses in the Medicare program, the FY 1996 financial statement audit process gave us our first statistically valid error rate in our Medicare fee for service program. Although 98% of the claims in FY 1997 were paid correctly based on information submitted on the claim, when subsequent medical documentation was requested from providers and the services were reviewed, the HHS Inspector General found that the error rate was between 7 and 16%. Of the errors identified through this "look behind" review of claims, the Inspector General estimated that approximately 44% of the errors were due to insufficient or missing medical documentation. Another 37% of the errors were due to a lack of medical necessity. The audit demonstrated the need for HCFA to increase oversight to ensure provider compliance with Medicare reimbursement rules and regulations.

In FY 1998 the OIG reported HCFA's estimated claims payment accuracy in their audit, "Improper Fiscal Year 1998 Medicare Fee-for-Service Payments"(A-17-99-00099). The audit found an estimated payment error of $7.8 to $17.4 billion of the $176.1 billion in processed fee-for-service claims paid by HCFA in FY 1998, with a midpoint of $12.6 billion. The overwhelming majority of these improper payments were detected through medical record reviews coordinated by the OIG. When these claims were submitted for payment to Medicare contractors, they contained no visible errors. The OIG found an estimated improper error rate of 4.4 to 9.9% with a midpoint of 7.1 percent. These errors were identified through this look-behind review of claims by the medical review staff and the Peer Review Organizations. Medicare, like other insurers, makes payments based on a standard claims form.

Providers are supposed to retain supporting documentation and make it available upon request.

The complete report is available on the HHS, OIG web site at www.hhs.gov/progorg/oig/.

Medicare Fee-for-Service Estimated Error Rates			
	FY 1996	**FY 1997**	**FY 1998**
Midpoint Dollar Estimate	$23.2 billion	$20.3 billion	$12.6 billion
Midpoint Percentage Estimate	14%	11%	7.1%

CLAIMS PAYMENT ACCURACY IMPROVES SIGNIFICANTLY

This is the third year that an error rate has been estimated for Medicare fee-for-service claims payments and the FY 1998 error rate estimate showed significant improvement over prior years. The accompanying table shows the statistics for each of the three years. The $10.6 billion reduction in improper payments since FY 1996 is primarily due to an $8.7 billion drop in documentation errors, according to the HHS Inspector General report, "Improper Fiscal Year 1998 Medicare Fee-for-Service Payments."

"[This] report by the Inspector General is welcome proof that our zero tolerance policy against waste, fraud and abuse is paying off. We still have a big job to do in eliminating improper Medicare payments, but with a 45 percent reduction in improper payments in just two years, we are making real progress."

Secretary Donna E. Shalala

Improper payments could range from inadvertent mistakes to outright fraud and abuse; the portion of the error rate attributable to fraud can not be quantified.

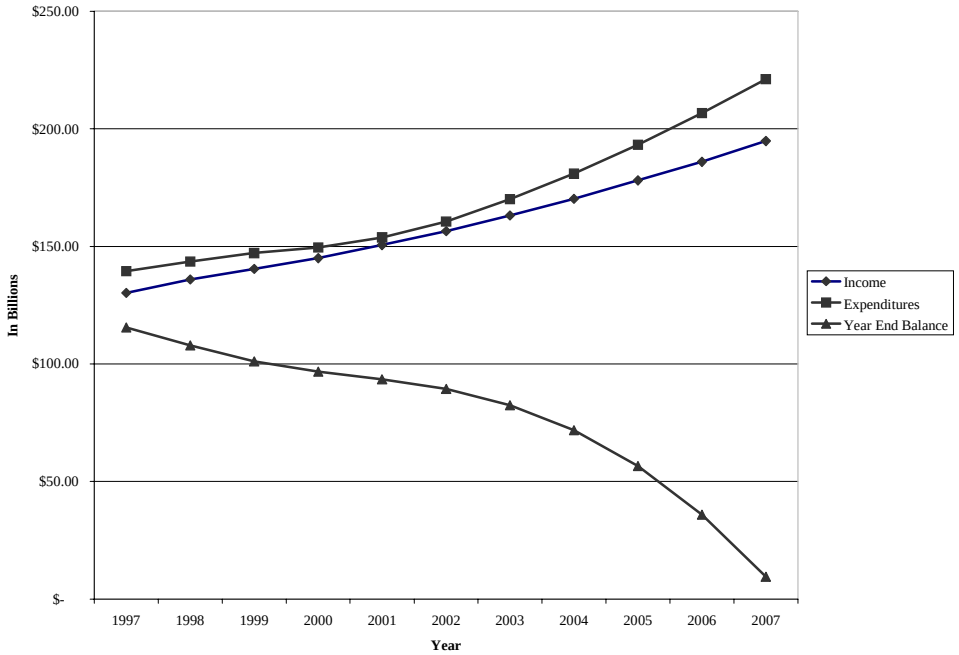
Also in September, HCFA, as a prevention strategy, entered into a voluntary agreement with two Fortune 500 companies to conduct data matches to ***reduce overpayments when Medicare is the secondary payer***. If Medicare records do not show that a beneficiary has other insurance, Medicare can mistakenly pay claims that should have been paid by the primary insurance company. HCFA has undertaken a number of other initiatives to avoid incorrect payments in this situation. The Initial Enrollment Questionnaire solicits data about other primary health insurance coverage from newly enrolled Medicare beneficiaries. A data match, in collaboration with the Internal Revenue Service and the SSA, is used to develop leads where federal tax returns show wages reported for beneficiaries or their spouses who might have group health insurance and for whom Medicare is paying for health care services. Progress will need to continue to be made to reduce these overpayments.

MEDICARE TRUST FUND SOLVENCY

Medicare Part A, the Hospital Insurance (HI) trust fund, is financed primarily by payroll taxes paid by workers and employers. The taxes paid each year are used mainly to pay benefits for current beneficiaries. Income not currently needed to pay benefits and related expenses is held in a trust fund and invested in U.S. Treasury securities. Although improved substantially by the Balanced Budget Act of 1997 (BBA), the short-range (the next 10 years) financial status of the trust fund remains unsatisfactory overall. This trust fund is expected to be depleted during 2008 because of increases in health care costs and utilization that generally exceed increases in the payroll taxes that support the program. The payroll tax rates are set in law.

	Statistics From HI Trustee Reports	
	1997 (pre BBA)	1998 (post BBA)
% increase in beneficiaries		
from previous year	1.4%	1.4%*
over 10 years	22.4%	22.0%
$ total benefits	$128.6 billion	$137.8 billion
% increase in total benefits (from previous year)	10%	7%
Average expenditure per enrollee	$3,400	$3,600
% increase in avg. enrollee expenditure (from previous year)	9%	6%
Workers per beneficiary ratio		
At inception (1966)	4.47	4.47
Actual	3.9	3.9
Projected for 2010	3.6	3.6
Projected for 2030	2.3	2.3
Projected for 2060	2.0	2.0
Deficit of expenditures over income	($4.2 billion)	($9.3 billion)
Projected fund depletion date	2001	2008

Estimated HI Trust Fund Operations

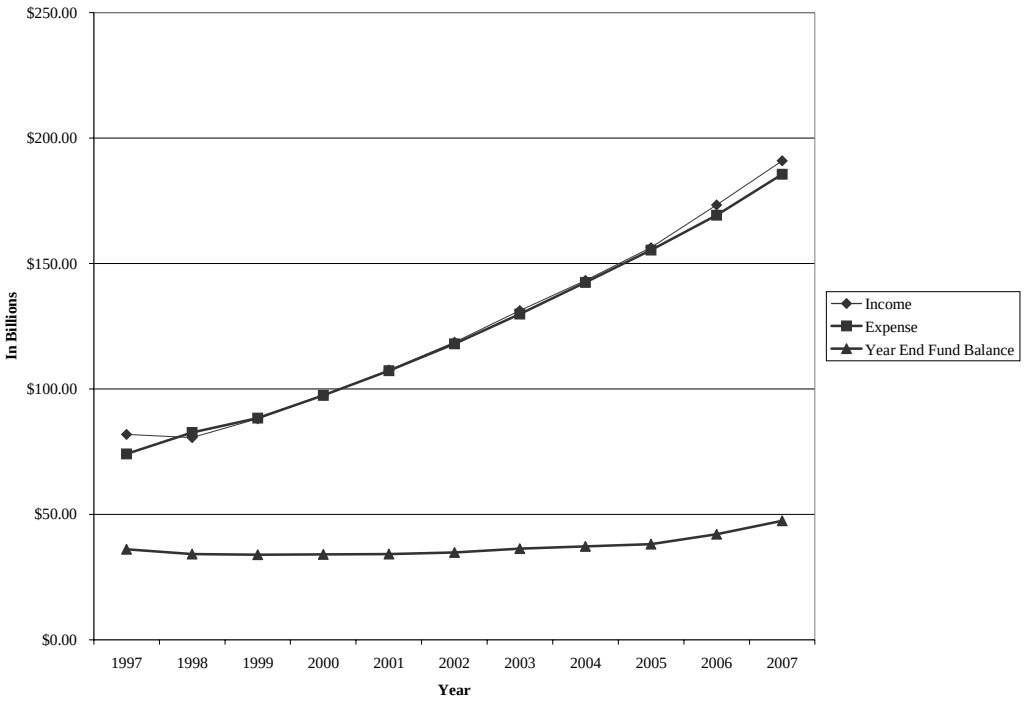


Source: 1998 HI Trustee Report, Table I.E1.

Medicare Part B, the Supplementary Medical Insurance (SMI) trust fund, pays for primary physician and outpatient care, and is financed primarily by appropriated funds (73%) and monthly premiums paid by beneficiaries (24%). Income not currently needed to pay benefits and related expenses is also held in a trust fund (separate from the hospital insurance trust fund) and invested in U.S. Treasury securities. The reduction in certain costs resulting from the BBA are more than offset by increases in other costs including the transfer of home health care costs from the HI to SMI program and new SMI benefits. In fact, the costs for this trust fund in 1998 and later will exceed those that would have occurred in the absence of the BBA. However, this trust fund is expected to remain adequately financed into the indefinite future because beneficiary premiums and government contributions are set (by law) to meet expected costs each year. Program costs have generally grown faster than the Gross Domestic Product and this trend is expected to continue under present law.

	Statistics From SMI Trustee Reports	
	1997 (pre BBA)	1998 (post BBA)
% increase in beneficiaries		
from previous year	1.3%	0.9%
over 10 years	18.4%	17.2%
$ total benefits	$68.6 billion	$72.8 billion
% increase in total benefits		
from previous year	6%	6%
over 5 years	45%	48%
Average expenditure per enrollee	$1,902	$1,999
% increase in avg. enrollee expenditure (from previous year)	4%	5%
Excess of income over expenditures	$15.2 billion	$7.8 billion

Estimated SMI Trust Fund Operations



Source: 1998 SMI Trustees Report, Table I.E1.

❖ **We strove to improve the health status of American Indians and Alaska Natives.**

In direct partnership with the tribes and in recognition of their expanding role in developing and managing the health needs of ***American Indians and Alaska Natives*** (AI/AN), IHS is working to provide access to basic health services, including the assurance of adequate facilities and equipment for the provision of health services and adequate support services to the tribal health delivery system. In FY 1998 under the ***Hospitals and Clinics Program***, IHS and the tribes provided essential services for inpatient care, routine and emergency ambulatory care; and support services. The program includes initiatives targeting special health conditions that affect AI/ANs.

Unintentional injuries continue to be the leading cause of death for Indian people up to the age of 45. The Safe Tribal Communities Campaign for AI/AN youth was reactivated in fiscal year 1998, to address aspects of this issue. The campaign seeks to involve youth in actively reducing vehicle-related injuries and injury risks in their communities. IHS is focusing on increasing tribal community capacity building and more inter-tribal collaboration on injury prevention. To assist tribes in building infrastructures for injury prevention capacities, the IHS awarded 3-year grants totaling $304,000 beginning in FY 1997 to 13 tribes.

In 1998, more than $30 million was obligated for 286 grants awarded to IHS facilities, Indian tribes/ tribal organizations and urban Indian organizations to address the prevention and treatment of diabetes. Diabetes continues to grow in epidemic proportions in Native American communities. In some AI communities, up to half of the adults have diabetes. Diabetes is 4-8 times more common among AIs compared to the general U.S. Population. Through these grants, diabetes prevention and treatment programs will reach more than 100,000 AI/ANs suffering from diabetes as well as another 30,000 to 50,000 who are at risk.

Fifteen to twenty federal and tribally operated health care facilities participated in statewide training conferences on improving the healthcare response to ***domestic violence***; only 47% of federal facilities with urgent care units or emergency departments have policies /protocols for handling domestic violence cases.

Approximately 27,400 Indian homes lack either a safe water supply or adequate sewage disposal system, or both. In 1998, essential new ***sanitation facilities*** were provided to 7,784 homes and upgraded facilities to 6,589 homes.

Support from all available sources is essential to meet the needs of the Indian people that the IHS, the tribes, and the Urban Indian Programs serve. In FY 1998 the IHS provided support to the National Indian Health Board to coordinate and manage a national meeting to address key policy issues in State Medicaid reform. The meeting included representatives from HCFA, the tribes, the Urban Programs, and IHS. In addition, OMB recently approved Medicare and Medicaid reimbursement rate changes for IHS facilities. The new rates approved for calendar year 1998 were based on a select number of Medicare hospital cost reports developed by the IHS and reviewed by HCFA. These efforts enable the IHS to be appropriately reimbursed for services provided to Indian people who are entitled to Medicare and Medicaid health programs.

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Under the Older Americans Act, the Administration on Aging provided funding to 232 AI tribal organizations and AN organizations representing more than 300 tribes. This funding provides supportive and nutrition services, including 2.7 million congregate and home-delivered meals and nutrition education to older Native Americans. These services are responsive to the cultural diversity of Native communities and comprise a critical component of comprehensive community-based social and health-related services in Native communities.

GOAL 4: IMPROVE THE QUALITY OF HEALTH CARE AND HUMAN SERVICES.

The quality of health and human services needs to improve continually to address constantly changing problems. HHS accomplishes this goal by a wide range of quality improvement activities designed to provide better ways of addressing the changing problems that confront the health and human service delivery system, such as changes in family structures, demographics and financing of health services.

❖ We promoted the appropriate use of effective health services.

Significant improvements in health, as well as reductions in costs associated with unnecessary remedial care, could be achieved by improving the extent to which physicians and other practitioners deliver the most appropriate treatments. In FY 1998, HHS continued to evaluate the outcomes of the investments that the agency funds.

AHCPR awarded new research grants to assess the ***outcomes and cost effectiveness*** of : Health plans on hypertension and diabetes care; quality improvement in nursing homes; multi-method assessment of Medicaid managed care; and cost effectiveness analysis of surgery in Epilepsy-Cease.

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❖ We increased consumer's understanding of their health care options.

On February 20, 1998, HHS launched a nationwide effort to help patients rate their health plans and to help consumers choose among plans. The effort is built on a new survey tool, the ***Consumer Assessment of Health Plans*** (CAHPS), that provides a consumers-eye view of the care and service they receive from health plans. The survey asks how easily beneficiaries can access specialists and emergency care services and seeks information on the general level of consumer satisfaction. In 1998, CAHPS was adopted by the Office of Personnel Management for use by the Federal Employees Health Benefits Program to survey Federal employees and report back the findings of the survey to them to help in the selection of health plans during the Federal open season.

In April, 1998, the Office on Women's Health under the Office of the Secretary, launched an enhanced web site for the ***National Women's Health Information Center.*** The web site is at http://www.4woman.gov. It provides access to a wide variety of women's health resources and services, such as Federal information, clearinghouses, health research sources, current health news, upcoming events and links to a variety of other resources.

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❖ We improved consumer protection.

In June, 1998, HHS established a series of new patient protections for the 39 million beneficiaries of ***Medicare*** to bring Medicare into compliance with the Administration's ***Consumer Bill of Rights***. These new protections include access to emergency services when and where the need arises, patient participation in treatment decisions, and access to specialists.

In addition, the 33 million (average number of enrollees in 1998) ***Medicaid*** enrollees also are being assured essential protections in the ***Consumer Bill of Rights***. In September, 1998, HCFA published a Notice of Proposed Rulemaking adding new patient protections such as access to specialists and an expedited independent appeals process to bring the program into compliance with the patient's bill of rights, where possible.

Also the CAHPS survey tool was merged with another health care quality tool, the Health Plan Employer Data and Information Set Member Satisfaction Survey and will be used by the National Committee for Quality Assurance to evaluate and accredit commercial managed plans.

On July 21, 1998, ***a nursing home initiative*** was unveiled to enhance protections for nursing home residents, including tougher enforcement of nursing home rules and strengthened oversight of States nursing home quality and safety responsibilities. HCFA has implemented a new monitoring system and has given new instructions to States on how to handle problem nursing homes and nursing home chains.

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Ombudsman programs in every state and 570 local areas helped resolve nursing and board-and-care home residents' problems; provide information to residents, potential residents and their loved ones; and advocate on behalf of these health care consumers. Recently the Secretary reported to Congress that in 1996, ombudsmen nationwide handled over 179,000 complaints made by over 116,000 individuals and provided information to another 186,000 people. The National Long-Term Care Ombudsman Resource Center is operated by the National Citizens' Coalition for Nursing Home Reform in conjunction with the National Association of State Units on Aging. With funding provided by the HHS' AoA, the Center provides on-call technical assistance and intensive annual training to enable ombudsmen to be effective in their demanding work.

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In FY 1996, 81% of the cases closed by Ombudsman programs involved nursing homes. The five most frequent nursing home complaints concerned:

- accidents, improper handling,
- requests for assistance needed,
- personal hygiene neglected,
- lack of respect for residents, poor staff attitudes, and
- lack of adequate care plan, resident assessment.

Ombudsman programs protect senior citizens' health care rights.

GOAL 5: IMPROVE PUBLIC HEALTH SYSTEMS.

The infrastructure of public health systems needs to be preserved and improved to conduct the interventions that save lives and ameliorate suffering. HHS contributes to an effective public health system by supporting improvements in training staff, encouraging the sharing of reportable disease information electronically, and ensuring that food and drug safety systems exist and work.

❖ **We improved the public health system's capacity to monitor the health status and identify threats to the health of the Nation's population.**

The ***Medical Expenditure Panel Surveys*** (MEPS), ($36.3 million budgeted for FY 1998) which is actually an interrelated series of surveys, was enhanced and expanded and is now a continuous data collection effort, instead of periodic surveys once every 10 years. This provides a more current data resource to capture the changing dynamics of the health care delivery and insurance system. As a result, key findings from MEPS data released in 1998 yielded this useful information for decisionmakers:

- Nearly 18% of the U.S. population had no usual source of health care in 1996.
- Hispanic-Americans (30%), young adults aged 18-24 years. (34%), and the uninsured under 65 years of age (38%), were the most likely to lack a usual source of care during FY 1996.
- Approximately 12% of all American families experience barriers to receiving needed health care services.

The web site for MEPS is:
http://www.meps.ahcpr.gov

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The ***"Health United States 1998 with Socioeconomic Status and Health Chartbook,"*** was published. It is the 22nd such report on the health status and national trends in health statistics. The special topic chartbook addresses the health status, risk factors, and health care access and utilization of children and adults. More information in the report is available at http://www.cdc.gov/nchswww/products/products.htm.

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Environmental health monitoring at hazardous waste sites was improved this past year when ATSDR and its public health partners addressed 38 of 234 hazardous waste sites where they have been unable to conduct necessary public health activities.

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Special care must be taken to prevent exposure and adverse human health effects from hazardous substances.

HHS worked actively with stakeholders to develop an agenda for disease prevention and health promotion efforts from 2000-2010. ***Healthy People 2010*** is scheduled to be released in January 2000. It is the successor to the long-standing Healthy People 2000, which is the basis for the current "national objectives" that have been referred to throughout this document. They support and exert an influence on the GPRA strategic objectives and performance plan, but are longer-term and are focused on national, rather than agency achievements. To increase the potential impact and use of Healthy People 2010:

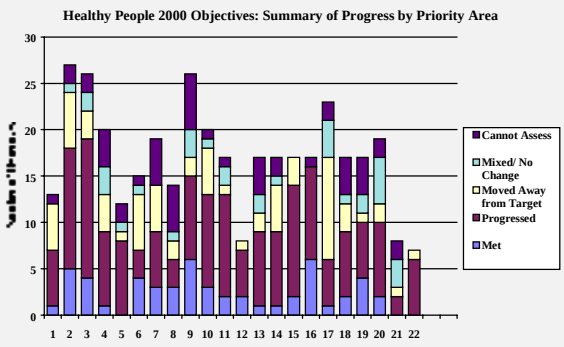
- In March 1998, the HHS working group issued a report on the potential uses of leading health indicators, criteria that might be applied to leading health indicators, and possible candidates for leading health indicators that will be part of Healthy People 2010.
- Because these are national objectives, not just HHS objectives, the public has been involved in their development through focus group sessions, national and regional public meetings, and a web site for reviewing draft objectives and commenting on them.

The most recent data available on the progress achieved in those areas being monitored by the Healthy People 2000 Program are found in the following table and chart. More information can be found at: http://odphp.osophs.dhhs.gov/pubs/hp2000.

Healthy People 2000 Objectives:
Summary of Progress by Priority Area

Priority Area	Met	Progressed	Moved Away from Target	Mixed/ No Change	Cannot Assess	Total
1. Physical Activity and Fitness	1	6	5	0	1	13
2. Nutrition	5	13	6	1	2	27
3. Tobacco	4	15	3	2	2	26
4. Substance Abuse: Alcohol and Other Drugs	1	8	4	3	4	20
5. Family Planning	0	8	1	1	2	12
6. Mental Health and Mental Disorders	4	3	6	1	1	15
7. Violent and Abusive Behavior	3	6	5	0	5	19
8. Educational and Community-Based Programs	3	3	2	1	5	14
9. Unintentional Injuries	6	9	2	3	6	26
10. Occupational Safety and Health	3	10	5	1	1	20
11. Environmental Health	2	11	1	2	1	17
12. Food and Drug Safety	2	5	1	0	0	8
13. Oral Health	1	8	2	2	4	17
14. Maternal and Infant Health	1	8	5	1	2	17
15. Heart Disease and Stroke	2	12	3	0	0	17
16. Cancer	6	10	0	0	1	17
17. Diabetes and Chronic Disabling Conditions	1	5	11	4	2	23
18. HIV Infection	2	7	3	1	4	17
19. Sexually Transmitted Diseases	4	6	1	2	4	17
20. Immunization and Infectious Diseases	2	8	2	5	2	19
21. Clinical Prevention Services	0	2	1	3	2	8
22. Surveillance and Data Systems	0	6	1	0	0	7
Total:	53	169	70	33	51	376
	14.1%	44.9%	18.6%	8.8%	13.6%	100.0%

SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics.



Source: *HP2000 Program, 1998*

❖ **We worked to ensure food and drug safety by increasing the effectiveness of science-based regulation.**

Americans have the world's safest food supply and HHS worked to ensure the safety, reliability, and efficacy of drugs and medical products.

Under the ***Prescription Drug User Fee Act*** (PDUFA) manufacturers paid for improved processing procedures and time for new drug and biologics (the study of blood and blood products) applications. The objective of PDUFA is to expedite the application review process, without compromising safety and sacrificing the quality that Americans expect. The FDA had committed to certain performance goals in response to these additional resources, and has met or exceeded these goals for FY 1995, FY 1996, and FY 1997. This success occurred even with unexpected, continued growth in the number of marketing applications filed for review.

As a result, in 1997 Congress reauthorized PDUFA under the Food and Drug Modernization Act for another five years (known as PDUFA II).

In 1998, user fee revenues from drug reviews financed approximately 708 more FTEs to help meet FY98 performance goals of expediting the approval of new drugs. The PDUFA goals must be met for each of the fiscal year cohorts. A cohort is defined as the group of submissions received by the Agency during a particular fiscal year. The agency is allotted time set by PDUFA (plus three months if a major amendment is received-the three month extension is only on the original New Drug Applications (NDA) and is only one time) to review and act on a submission.

With each passing cohort year, the performance goals have become more stringent. Seventy percent of the FY 1995 submission cohort had be reviewed and acted upon "on time"; 12 months for NDAs and efficacy supplements, but only 6 months for resubmissions and manufacturing supplements. The goals increased to 80% and 90% for FYs 1996 and 1997 submission cohorts, respectively. In FY 1998, PDUFA II required the complete review of 90% of standard original NDAs and efficacy supplements within 12 months of receipt, 90% of priority original NDAs, priority efficacy supplements, and manufacturing supplements requiring prior approval within 6 months of receipt, and 90% of resubmitted original applications within 6 months of receipt.

Fiscal Year 1997 Drug Submission Cohort as of 9/30/98

Type of Submission	Number of Submissions Filed with FDA	Number of Reviews "OnTime"	Percent of Reviews "OnTime"
New Drug Applications	120	119*	99%
Resubmissions	87	84	97%
Efficacy Supplements	147	145	99%
Manufacturing Supplements	1,262	1,241	98%

*Pending NDA was not overdue as of 09/30/98. The review time was extended for an additional 3 months until November 1998 due to the one-time major amendment extension allowed under PDUFA.

For all open cohorts during FY 1998, FDA took 217 actions on NDAs, 107 of which were approvals. The median approval time was 12 months - a 24% decrease in median approval time compared with FY 1997. Sixty-three of these NDAs were approved in 12 months or less. Actual performance results for the FY 1998 cohort will be available within 6 to 12 months. The count of FY 1998 submissions assumes that submissions received in the last two months of FY 1998 were filed; FDA makes a filing decision within 60 days of an original application's receipt. All calculations of PDUFA review times are made, however, from the original receipt date of the filed application.

The same FY 1998 goals applied to blood and blood products approvals and the level of performance is also at the same equivalent high level as PDUFA drug approvals.

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The FY 1998-99 ***National Food Safety Initiative*** is intended to build a national early warning system for hazards in the food supply by enhancing capacity for surveillance and outbreak investigations at the state and federal levels and by linking state health departments and federal agencies with sophisticated computer and communication systems.

- CDC demonstrated, through evaluation of laboratory training programs, significant improvements in laboratory methods for investigating foodborne illnesses.
- Developed and signed a memorandum of understanding in May 1998 between the Department of Health and Human Services (including FDA), USDA, and the EPA which created a Food Outbreak Response Coordinating Group (FORC-G). FORC-G will increase coordination and communication among federal, state, and local food safety agencies; guide efficient use of resources and expertise during an outbreak and; prepare for new and emerging threats to the U.S. food supply.

PulseNet: Pathogen Identification System

The PulseNet system was put to work in the first year of the Food Safety Initiative to identify common sources of illnesses and speed outbreak traceback and containment. State laboratory, CDC, FDA, and USDA PulseNet systems determine bacterial subtypes with a high degree of accuracy and transmit the information digitally to a central computer at CDC. The CDC computer can match a newly submitted pathogen fingerprint to those in a databank, and can confirm whether or not disparate outbreaks are connected by a common source. In FY 1998, CDC electronically linked with 16 States for enhanced surveillance and control activities for *E. coli 0157:H7.*

During 1998, PulseNet connected two seemingly independent *E. coli O157:H7* outbreaks in Michigan to a common source—alfalfa sprouts; found that *E. coli O157:H7* illnesses in two different states shared the same DNA fingerprints, accelerating traceback to a single mesclun lettuce packer; helped confirm that about 50 cases of *E. coli O157:H7* in Wisconsin were attributable to cheese curds from a single facility, after initial inspections did not reveal the source of contamination; and connected *E. coli O157:H7* outbreaks from ground beef with specific processors.

HHS programs help to ensure food safety.

- In September 1998, FDA hosted an important meeting of food-safety officials from all 50 states, the District of Columbia, and other localities, Puerto Rico, the Association of Food and Drug Officials, FDA, USDA, and CDC to better integrate appropriate food-safety functions at the local, state, and federal levels. Integration efforts focused on inspection, analytical methodology, laboratory utilization, and response to disease outbreaks. The goals of this integration effort are better use of laboratory resources and investigative expertise and faster response to and control of foodborne illness outbreaks.

FoodNet: Foodborne Disease Tracking System

At the seven FoodNet offices located throughout the country, state and federal epidemiologists look for signs of foodborne illness by monitoring clinical laboratories in their respective regions for lab-confirmed infections with seven bacteria and two parasites most often associated with foodborne illness. Two major findings from FoodNet data were determined in FY 1998: (1) Campylobacter is now the most common cause of confirmed foodborne illness, and (2) Listeria infections have the highest hospitalization rates and cause more deaths than any other pathogen tracked.

FDA has also improved ***food safety*** in FY 1998 by implementing the Hazard Analysis and Critical Control Point (HACCP), a preventive approach to a food safety that applies science-based controls from raw materials to finished product. FDA:

- Expanded its food safety inspection and investigational regulatory force to include an additional 61 inspectors and investigators and 19 microbiologists.

- Implemented the HACCP food safety system for the seafood industry in December 1997. HACCP requires seafood processors, repackers and warehouses—both domestic and foreign exporters to this country—to focus on identifying and preventing hazards that could cause foodborne illnesses.

- Inspected 3,876 domestic seafood establishments. FDA expects to meet its goal of inspecting all remaining seafood processors by the end of the calendar year. Also, approximately 940 HACCP inspections were conducted of seafood importers.

- Required warning labels on unpasteurized or untreated fresh apple juices became effective in September 1998. Warning labels for all other unpasteurized or untreated juices are required by November 1998.

- Proposed that juice manufacturers adopt HACCP programs at their plants based on the record of illnesses and injuries associated with consumption of contaminated juice products. FDA is in the process of developing a final regulation.

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GOAL 6: STRENGTHEN THE NATION'S HEALTH SCIENCES RESEARCH ENTERPRISE and ENHANCE ITS PRODUCTIVITY.

Improvements in health are grounded in knowledge acquired through research. HHS sets the pace for the world in medical, epidemiological (incidence, distribution, and control of disease), behavioral, and health services research. We sponsor and conduct public and private research through strong, sustained public support for health sciences.

❖ **We improved the understanding of normal and abnormal biological processes and behaviors.**

This year brought news of significant gains in biomedical research.

Advances in understanding ***HIV and AIDS*** have resulted from several new studies that revealed some of the mechanisms by which HIV undermines the immune system. The simple act of HIV binding to immune cells increases infectivity, virus production, and immune system damage. Also, HIV "rebounds" in people who stop taking triple-drug therapies because HIV remains hidden (latent) in a patient's lymph nodes.

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Genetic discoveries have proceeded at an incredible pace. The connection of a human disease to a particular gene is an important breakthrough because researchers can then begin to learn how the gene normally functions in the body, and then how an altered form of the gene can cause disease. Such crucial knowledge can in turn suggest new diagnostic, therapeutic, and preventive approaches to disease. In the past year, scientists have discovered a number of genes involved in serious human diseases and conditions, including:

- Alagille syndrome, a rare childhood disease associated with a wide range of birth defects,
- Alzheimer's disease development after the age of 65,
- Hirschsprung Disease, which causes impaired intestinal function,
- A form of progressive deafness,
- Non-syndromic recessive deafness, and
- Increased risk of bladder cancer among smokers.

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Pain is associated with many medical disorders and can be extremely debilitating, accounting for 40 million physician visits per year for "new" pain. Two chemicals have been identified that may be responsible for the body's reaction to moderate-to-intense pain. These findings may lead to the development of a new class of pain medications.

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In 1996 the primary and secondary ***syphilis*** rate of the United States was 30 times that of Canada. Scientists have recently published the full DNA sequence of the bacterium that causes syphilis. This blueprint can be used to devise diagnostic tests that are more accurate and suggests targets for new, more specific antibiotics to treat syphilis.

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Fruit flies may shed light on ***drug and alcohol addiction*** since they respond in the same way to "crack" cocaine and alcohol as do humans. They are much easier to work with and less costly to maintain than other model organisms. Studies of alcohol intoxication of fruit flies provide evidence that a well-studied chemical in the brain plays an important role in response to alcohol.

These tiny flies may also become an important model to study the effects of cocaine.

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New emphasis on the biology of ***brain disorders*** reflects the extraordinary rate at which the neurosciences are growing. New imaging techniques are enabling researchers to view the brain in action; an understanding that can be applied to develop medications to combat drug craving.

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❖ **We improved the prevention, diagnosis, and treatment of disease and disability.**

The decline in ***AIDS*** deaths is primarily due to the continuing impact of highly active antiretroviral therapy in helping people with HIV live longer and healthier lives. As of June 1998, NIH-supported researchers had evaluated 23 vaccine candidates and 10 adjuvants (substances incorporated into a vaccine that boost specific immune responses to the vaccine) in 3,200 volunteers in 49 clinical trials. On June 3, 1998, the FDA granted permission to a firm for conducting the Nation's first phase clinical trial for an AIDS prevention vaccine. In April, HHS determined that needle exchange programs can be an effective part of a comprehensive strategy to reduce the incidence of HIV transmission without encouraging the use of illegal drugs.

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Age adjusted death rates from HIV infection in the United States declined an unprecedented 47% from 1996 to 1997, and HIV infection fell from 8th to 14th among the leading causes of death in the U.S. over the same time. The 1997 rate of 5.9 deaths per 100,000 is less than half the 1992 rate (12.6) and almost one-third the rate in 1995, the peak year (15.6).

On March 12, 1998, CDC and NIH announced that the incidence and death rates for all ***cancers*** combined and for most of the top 10 types of cancer declined between 1990 and 1995. These rates reverse an almost 20 year trend of increasing rates of cancer cases and death in the United States. The report showed that incidence rates declined for most age groups, for both men and women, and for most racial and ethnic groups. CDC and NIH continued to be actively engaged in cancer prevention and treatment research.

- Melanoma, a particularly metastatic and often deadly form of ***skin cancer***, may one day be treated with a vaccine. NIH reports that a clinical study shows that a cancer vaccine can work to trigger an immune response to a tumor, and paves the way for more extensive trials of this and other immunotherapies for cancer.

- NIH also reported that a ***breast cancer*** prevention trial ended 14 months early when investigators determined that tamoxifen reduced by 45% the incidence of breast cancer in participants. Although the results are promising, tamoxifen does increase other risks.

- NIH informed CDC in June 1998 that ***methyleugenol*** was a carcinogen. The amount of human exposure was unknown so CDC developed a method to measure this compound.

Also, in FY 1998, CDC developed and improved analytical methods to measure about ***50 toxic substances***. CDC will test individuals for these toxic substances in the National Health and Nutrition Examination Survey that is being conducted in FY 1999.

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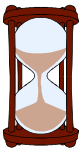
The incidence rate (of new cases) for all cancers combined declined an average of .7% per year from 1990 to 1995. Overall cancer death rates declined an average by about .5% over the same period.

CHALLENGES WE ARE ADDRESSING

Our Nation faces enormous challenges to the health and well-being of our citizens. The challenges we face are both programmatic and administrative. The programmatic issues may get more public attention, but the administrative infrastructure issues (such as the Year 2000 readiness of our computer systems) are vital to the efficient delivery of health and social services.

PREPARING HHS FOR THE YEAR 2000



Overview: The Year 2000 presents a tremendous challenge to computer systems around the world, including the computer systems at HHS. Most computers were designed or programmed to represent the year with only two digits. When these computers see "00" as the year on January 1st, 2000, they will erroneously assume the year is 1900. This Year 2000 (Y2K) problem may cause these computers to stop running or to start generating erroneous data. For example, erroneous data can result in problems with the processing and transmission of general information, electronic funds, and the operations of computer-controlled mechanical devices. There are three ways to correct this date problem: replace a computer system with a compliant one, repair the date fields to allow for the Year 2000, or retire the system if it is no longer needed.

All HHS programs are affected to some degree by the Y2K problem. For this reason, the Secretary of HHS has made the Year 2000 Job #1. All parts of HHS, including staff with expertise in information systems, budget, human resources, and acquisition management, are working to ensure that HHS information systems are able to recognize the Y2K and that we are able to continue to exchange data with our many partners. HHS is also working to inform the health care and human service communities about the Y2K issue to ensure that their equipment and facilities are Y2K compliant.

In the November quarterly report to Congress (for the reporting period ending September 30, 1998), HHS had 289 mission-critical systems. These are systems that are vital to the day-to-day operations of the Department's core business areas and processes. Mission critical systems pay Medicare benefits; provide billions of dollars in grant payments; collect and analyze epidemiologic, clinical trial, and other public health information; and track health care spending and other data. As of September 30, 1998, 51 % of HHS' mission critical systems were Y2K compliant. (For the report period ending December 31, 1998, 85 % of HHS' mission critical systems were Y2K compliant).

Medicare contractors operate many mission-critical systems controlling Medicare payments to health care providers. The majority of these systems are expected to certify as Y2K ready by the end of December 1998. While intense work is still needed in some areas, the Department is still planning to have all HHS internal and external mission critical systems to be Y2K ready by the government-wide deadline of March 31, 1999. HHS has taken a series of strong administrative actions, such as reprogramming of available fiscal resources where necessary, to meet the Y2K compliance deadline.

HHS has estimated that the total cost for ensuring HHS systems are Y2K compliant is $781 million over FYs 1996 and 2000. To help the Medicare program meet the Secretary's goal of achieving full Y2K compliance, HHS allocated an extra $42.1 million to HCFA in FY 1998 by drawing on discretionary funds from each HHS operating division, increasing total HCFA spending to $148 million. In FY 1999, HHS is receiving $282 million in emergency funds for Y2K conversion, $205 million of which is targeted for HCFA, providing total HCFA FY 1999 spending of $288 million.

HHS is working diligently to ensure that all work to address the Y2K problem is accomplished not only in HHS's internal systems, but also for the external interfaces with other federal, state, and local government agencies and HHS's private sector partners. In addition, almost all of the OPDIVs have completed the development of business continuity plans to ensure that all critical services to the public are not interrupted by unforeseen circumstances.

IMPLEMENTING THE BALANCED BUDGET ACT OF 1997

Under the Balanced Budget Act of 1997 (BBA), the Department is tasked with implementing a new Children's Health Insurance Program (CHIP), a new Medicare + Choice program, provisions to control Medicare benefit spending, and new fraud and abuse authorities.

HCFA has fully implemented more than half of the 335 individual BBA provisions affecting HCFA programs and made substantial progress on many of the remaining provisions. While working on the BBA, HCFA is simultaneously meeting the Y2K computer challenge. As recommended by independent consultants, HCFA has made the difficult choice to postpone a few BBA provisions that would have jeopardized HCFA's Y2K activity.

In FY 2000, HCFA will continue to work on the development of new payment methods, including prospective payment for home health agencies, inpatient rehabilitation facilities, and outpatient hospital care, and risk adjustment for Medicare +Choice plans. HCFA will also launch the new competitive bidding demonstration for durable medical equipment. HCFA's plans to educate beneficiaries about their choices include national distribution of a new Medicare handbook and holding local health information fairs to assist beneficiaries during the November 1999 open enrollment season. If Y2K renovations are completed ahead of schedule, we will make every effort to place these provisions back on their original timetable.

PROVIDING HEALTH CARE TO AMERICA'S UNINSURED CHILDREN

BBA provided the largest increase in funds available for health insurance for low-income children since the creation of Medicaid in 1965. HHS will be administering the nearly $40 billion set-aside program for children, which allows States to extend health coverage to millions of uninsured children by expanding their current Medicaid programs or by creating new health insurance plans. There will be many challenges related to the administration of the program under the various structures designed by the States.

CONTROLLING SPIRALING HEALTH CARE COSTS

The cost of health care in America is at an all-time high, due to the increasing costs of high-tech medical treatment, the increasing incidence of health problems, and an aging population. The Federal portion of these rising costs has contributed to a substantial portion of the national budget (21.6%) with outlays at the HHS, Department of Veterans Affairs, Department of Defense, and others. Medicare expenses now account for more than the entire Federal budget of 1966, the first year of the Medicare program. Fortunately, HHS has many programs that work synergistically to help identify ways to help keep health care costs down. These programs include those that: determine the most effective medical treatments; spread the word about illness prevention through exercise and nutrition; prevent foodborne illnesses; reduce the spread of infectious diseases; evaluate the impact of environmental toxins on health; and detect and prosecute health care fraud.

SUSTAINING THE MEDICARE TRUST FUNDS

BBA helped extend the solvency of the Medicare Hospital Insurance (HI) Trust Funds to the year 2008 as a result of savings achieved largely from curbing payments to hospitals and managed care plans. However, long term answers must still be found to maintain the viability of the trust funds as the Baby Boomers age. The Trust fund assets are invested in U.S. Treasury Securities which earn interest while Treasury uses those resources for other purposes (decreasing the Treasury's need to borrow from the public in order to finance the Federal debt). Unlike the assets of private pension plans, trust funds do not consist of real economic assets that can be drawn down in the future to fund benefits. Instead, they are claims on the Treasury that, when redeemed, will have to be financed by raising taxes, borrowing from the public, or reducing benefits or other expenditures. (When financed by borrowing, the effect is to defer today's costs to even later generations who will ultimately repay the funds being borrowed for today's Medicare beneficiaries.) The existence of large trust fund balances, therefore, does not make it easier for the Government to pay benefits.

EXPLOITING GENOMIC DISCOVERIES

Our children and grandchildren will undoubtedly benefit from novel medical treatments and preventive measures that have their origins in the Human Genome Project. This research program, aimed at deciphering the DNA sequence of humans, is a sterling example of national and international collaboration. Scientists across the Nation-supported by private industry, NIH, and the Department of Energy-and in Europe have already unraveled more than 10 percent of the human genome. They have also mapped more than 30,000 human genes (charted their relative locations on our chromosomes). Their work isn't finished however-most of the human genome sequence remains to be determined, and another 50,000 genes have yet to be mapped.

Researchers use the maps and sequence data to identify and locate genes involved in human disease. Once a disease gene is identified, the next challenge is to figure out the role it plays in human health and disease. This can entail many steps-such as learning whether the gene directs the production of a protein, and if so, determining the location, structure, function, and regulation of the protein in our cells, tissues, and organs. This information provides the foundation of developing new diagnostics, treatments, and prevention strategies.

The Human Genome Project will be accelerated by increasing capacity at major sequencing centers. Due to a number of methodological advances and increased resources, the expected completion date is now 2003, two years earlier than originally projected.

In FY 1999, the NIH began the Mouse Genomic and Genetics Project that will serve the research community by developing a laboratory tool for physiologists, developmental biologists, and neurobiologists to better understand mammalian biology. The research will be continued in FY 2000 to define the structure of the entire mouse genome and identify the function f mouse genes by studying gene mutations. Eventually the genomics of other organisms will be determined and used as "model systems" for learning about human genes and proteins and for testing new treatments.

ENGAGING OTHER DISCIPLINES IN MEDICAL RESEARCH

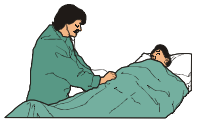
Few of the major discoveries in biology and medicine would have been realized without the contributions of scientific fields, which are often considered peripheral to medical research, such as physics, engineering and computer science. For example, optimal use of the vast amount of data being generated from genomic research will require increasingly sophisticated bioinformatics systems.

The integration of new genomic information with findings generated from classical biochemistry and cell and developmental biology-and the translation of this information into novel treatments, diagnostics, and preventions-requires the collaboration of researchers from many disciplines, including physicists, mathematicians, chemists, and bioengineers. Everyone benefits from multidisciplinary interactions. For example, in the development of bioimaging devices, imaging engineers better understand the clinical issues and questions that need to be addressed, and clinicians and researchers learn about the limitations and potential of the technology. This can lead to novel uses of imaging instruments and the generation of critical new knowledge and molecules, cells, tissues and organs.

Chemistry is another discipline that is critically important to medical research. Tomorrow's therapeutics will increasingly be molecules designed to interact very specifically and precisely with particular proteins. This approach is known as rational drug design, and chemists will be key participants in developing such agents. Rational drug design has already led to improvements of the protease inhibitors used in the treatment of HIV infection.

Structural biology is a rapidly growing field which aims to explain the activity of biologically important molecules in terms of their shape-and to use this knowledge to design new therapies or vaccines. One of the tools used to determine the structure or shape of proteins is synchrotron radiation. Synchrotrons are massive rings that produce X-ray beams that are thousands of times more intense than conventional X-ray beams. Scientists can analyze the X-ray patterns to determine the structural details of molecules with great precision. As biological researchers increasingly turn to structural biology, additional beamlines and highly trained experts to operate, maintain, and improve them will be essential.

REINVIGORATING CLINICAL RESEARCH

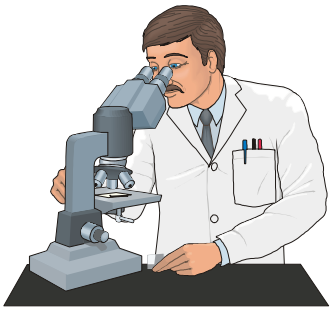


Translating medical research into improved human health is dependent upon a healthy clinical research enterprise. NIH's centers for clinical research, including the General Clinical Research Centers, need increased support to ensure the availability of the clinical research infrastructure vital to patient-oriented research. More clinical trials are needed to translate basic science into improved diagnostics, therapeutics, and prevention strategies. New programs to develop clinical biomarkers in immune diseases are required to guide the development of novel therapies and pediatric pharmacology programs need to be expanded to improve treatment regimens for children.

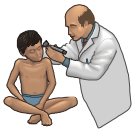
Much needed efforts to expand the training of physician scientists and avert a declining number of clinical researchers have begun in FY 1999 and will be continued. New grant programs to support the training of new/young physicians for successful careers in clinical research need to be continued and, in some cases, expanded. Grants to provide support to mid-level clinical researchers who serve as mentors for new investigators also need expansion. Additional research awards will allow academic institutions to develop didactic, multi-disciplinary training in the fundamentals of clinical research.

Efforts are also underway to expand the number of clinical trials as well as the number of patients participating in them. To provide the public with more useful information about clinical trials, the NIH is coordinating the establishment of a "one-stop shopping" database. This database will provide information about clinical trials such as what drug or intervention is being tested, who is eligible to participate, where the trial is located, and how to obtain additional information about the trial.

The NIH has also established the National Center for Complementary and Alternative Medicine (NCCAM). The NCCAM continues the efforts started by the Office of Alternative Medicine-to conduct rigorous and high-quality clinical research on complimentary and alternative medicine practices. Primary foci of NCCAM's efforts will be: evaluating the efficacy of widely used, natural products such as herbal remedies; studying the effectiveness of products used as nutritional and food supplements (e.g., mega-doses of vitamins); supporting pharmacologic studies to determine the potential interactive effects of these products with standard treatment medications; and evaluating practices such as acupuncture, chiropractic, and diagnostic and therapeutic application of electromagnetic fields.



ELIMINATING HEALTH DISPARITIES



Despite notable improvement in the overall health of the Nation, there continue to be health disparities across ethnic groups, socioeconomic strata, and people with different levels of education. Socioeconomic status (SES) is one of the most important determinants of health status, and begins to influence health even before birth; children born of low-SES parents have poorer health than children of high-SES parents have poorer health than children of high-SES parents. How socioeconomic and cultural factors contribute to the development of health beliefs and practices is not fully understood. It is thought that psychosocial factors such as environmental stress, depression, and available social supports exert as significant influence, but is not known in what manner and to what extent these interact with physiological risk factors to determine health.

A variety of factors play a role in the health disparities that exist among countries-especially between developed and developing regions of the world. The vast burden of premature mortality and disability falls disproportionately upon people in developing countries. Malaria, AIDS, and tuberculosis are just a few of the diseases that pose particular burdens for developing countries.

The demographic changes that are anticipated over the next decade further magnify the importance of addressing disparities in health status. After the year 2010, the numbers and proportions of elderly, especially those aged 80 and over, will rise rapidly in most developed and many developing countries. As our population ages, we can expect to see increases in illnesses such as Alzheimer's disease, heart disease, and cancer, which are more prevalent in elderly populations.

For progress to occur, research must be designed to examine these questions. There will be a renewed emphasis on research to understand the causes of disease; to identify and increase knowledge of risk factors for disease; to determine

reasons for health disparities that may be associated with race, ethnicity, gender, or socioeconomic status; and to understand the role of personal behaviors and environmental factors in health disparities. Sophisticated information from NIH research will benefit citizens in this country and around the globe.

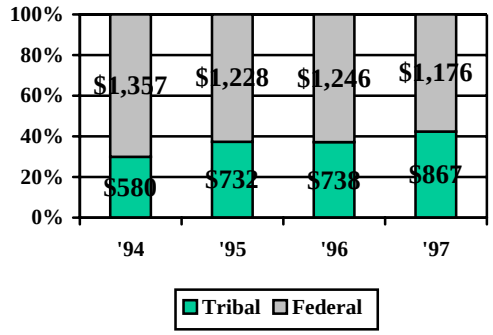
PROVIDING HEALTH CARES SERVICES TO AMERICAN INDIANS/ALASKA NATIVES

Balancing the goal of providing critical health care services while reducing administrative overhead and redirecting resources to tribal management will be a continuing challenge for the Indian Health Service (IHS) well into the next century. There has already been a significant transition to tribal management of health programs under Title I and III of Self-Determination legislation. In FY 1998, 44 percent of the IHS funding for services is under tribal control while significant proportions of Headquarters and Area administrative funding have been transferred to tribal programs.

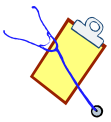
The IHS has committed to decentralizing control and expanding opportunities for consultation and collaboration with its local IHS, tribal and urban (I/T/U) stakeholders in setting priorities and the developing significant Agency policies. In FY 1998 this commitment was made operational through the "local level up" approach to the GPRA/Budget Formulation process and the collaborative stakeholder process used to determine the distribution of new diabetes funds. In addition, to assure this commitment is continued and expanded, the IHS developed Performance Indicator 24 in the FY 1999 performance plan. This indicator calls for the development of a formal policy for I/T/U consultation and participation. The policy will be approved by I/T/U representatives who will also complete a baseline survey to determine the level of satisfaction with the process.

The numbers for FY 1998 are $920 for Tribal and $1,179 for Federal for a total of $2,099.

Indian Health Service
Trends in Transfer to Tribal Control
($ in Millions)



ENSURING THE PRIVACY OF MEDICAL RECORDS



As the health care industry has become more automated with the electronic transmission of patient information for treatment and payment purposes, more and more people have access to information that used to be kept safe and private in our doctors' offices. Under the Consumer Bill of Rights and Responsibilities that was announced in February, 1998, HHS is working to ensure patient privacy and that information is shared only with those having a "need to know."

Health data standards for electronic health care commerce are mandated by the Health Insurance Portability and Accountability Act (HIPAA). The Statute requires HHS to adopt standards for both data and privacy of health insurance transactions. These standards will apply to the entire health care industry, rather than just to Federal programs and must meet the needs of the industry as a whole. HCFA will be called upon to facilitate the industry's implementation of the standards, and to implement the standards in the Medicare and Medicaid program. HIPAA also requires HHS to develop

regulations to protect the privacy of health information in the event that Congress fails to enact medical privacy legislation.

The first challenge to be faced will be the logistical challenge of analyzing and responding to the high volume of public comments on the proposed regulations. More than 24,000 comments were received for the four proposed rules published to date (medical information transactions, security and electronic signature standards; national provider identifier; and employer identifier number. Since these standards will apply to the entire health care industry, rather than just to Federal programs, these comments represent a wide range of viewpoints. The next challenge is to synthesize these disparate views into final rules that meet the needs of the industry as a whole.

> ***"Americans shouldn't have to trade in their privacy rights to get quality health care…. the way we protect our most sacred family secrets, our medical records, is erratic at best – and dangerous at worst. … We must act now with national legislation to address this serious threat."***
>
> **Secretary Donna Shalala**
> **September 11, 1997 before the Senate Committee on Labor and Human Resources**

PERSUADING THE PUBLIC TO ADOPT HEALTHIER LIFESTYLES

Americans are leading busier and more stress-filled lives than ever before. It is difficult to persuade them to take the extra time to prepare healthier meals when a high-fat, fast-food is far more convenient. Many Americans also say they have difficulty finding the time for regular exercise. In fact, recent statistics in a Healthy People 2000 Report indicates that a quarter of Americans lead a sedentary lifestyle. Yet diet and exercise are the two key elements in preventing illnesses. If more Americans could be convinced to have healthier diets and to incorporate more physical activity in their daily routine, our nation's physical and financial health would improve.

MANAGING FOR PERFORMANCE

The Government Performance and Results Act (GPRA) of 1993 provided HHS with an important tool to enable us to manage our organization and allocate our resources in ways that will most effectively help us achieve our mission. Our HHS strategic plan was completed in September, 1997, and our annual performance plans have been prepared for FY 1999 and for FY 2000, so that we can better manage for performance.

The range, complexity and diversity of programs implemented by the Department have contributed to one of the most critical challenges in the implementation of GPRA within HHS —the data issue. The absence of timely, reliable, and appropriate data is often a limiting factor in developing performance goals, objectives, and measures for HHS programs.

We are working to meet the challenges that we have encountered in such areas as: the diversity of data sources, the complexity of data systems, the need for reliance on achieving agreement with partners, the timeliness of data, the lack of agreement on program elements, the variability in technical sophistication, use of resources for data efforts and the multiple agencies that are involved in service delivery.

Many of the Department's critical data challenges are related to programs that are implemented in partnerships.

There have been some creative efforts within the Department to meet the data challenge. For example, the Maternal and Child Health (MCH)

Program has been able to achieve agreement from its state partners to identify a set of performance measures that will be used in state applications for the MCH block grant that are reported through an electronic reporting system. HHS has also organized a Data Council that plays a role in a number of areas, particularly in the development of Department-wide data collection, including coordination and consolidation of surveys. In addition, HHS has a large number of administrative and survey data systems to draw upon.

This continuing GPRA challenge will also affect the Accountability Report. Through the GPRA efforts to work with our partners on data solutions, the Accountability Report will continue to improve in the quantity and quality of performance data.